Washington State Health Care Authority

Washington State Health Technology Clinical Committee Meeting

Spinal cord stimulation continuation and bariatric surgery

May 17, 2024

DISCLAIMER

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

Christoph Lee	Morning. Good to see everyone.
Joseph Strunk	Good morning.
Chris Hearne	Good morning.
Sheila Rege	And, you let me know, we usually start at about 2 or 3 min after. I know it's 1 min after.
Josh Morse	Yeah, good morning, Sheila. Good morning, everyone. We have, I by my account, I think we have 7 committee members and Dr. Strunk the Clinical expert, so we have exceeded a quorum.
Sheila Rege	Very nice. Perfect.
Josh Morse	I think we're expecting one more committee member. Val, can confirm that.
Val Hamann	Yeah, I just promoted Dr. Sham.
Josh Morse	Excellent. So I think that's everyone we're expecting.
Sheila Rege	Okay. Well, thank you we have the agenda projected in front of us and in the interest of time. If everybody is comfortable that we've heard, the members of the committee, would do you want to do a sound check? But I think we're good right now. Val, what would you like or Melanie?
Val Hamann	Yeah, we could take a quick. Just head count to have that for our records.
Sheila Rege	Go ahead.

Val Hamann	So John Bramall, he is not here today. Clint Daniels. We're not hearing you. No, we still can't hear you.
Clint Daniels	Go out and back in. Okay.
Val Hamann	Yep, now we can hear you.
Josh Morse	There you go.
Val Hamann	Perfect. Janna Friedly.
Janna Friedly	Good morning.
Val Hamann	Chris Hearne.
Chris Hearne	Good morning.
Val Hamann	Conor Kleweno.
Conor Kleweno	Here.
Val Hamann	Christoph Lee.
Christoph Lee	Here.
Val Hamann	Laurie Mischley.
Laurie Mischley	Present.
Val Hamann	Sheila Rege.
Sheila Rege	Present.
Val Hamann	Jonathan Sham.
Jonathan Sham	Good morning.
Val Hamann	And then we have Dr. Strunk here as well. And we should actually have Tony Yen. I see him. I am promoting. Dr. Yen. Tony, are you able to, is your mic working and everything?
Tony Yen	Now it is. I was actually locked out for a while. Yeah.
Val Hamann	Perfect. Oh, sorry. Okay. We're ready to go, Josh.
Josh Morse	Great. I'm gonna share this presentation. Good morning. So here's our Let me know if you're seeing the right screen or the wrong screen.

Washington State Health Care Authority

Val Hamann Yeah, we see the correct one.

Josh Morse We are starting. So meeting reminders, this meeting is being recorded. The recording started a couple of minutes ago. Transcripts from these meetings are available on the website. You can see the transcripts from the past meetings here at a link from our web page, we don't use chat, any of us, in zoom for these meetings and It's disabled to the extent that we can. We will be using the raise hand function at a specific time for public comment during bariatric surgery during that topic. So some background on the program. The HTA program is administered by the Health Care Authority. This program brings evidence reports to the Health Technology Clinical Committee to make coverage decisions for certain medical procedures and tests based on the evidence of safety, efficacy and cost effectiveness. Multiple state agencies are participating in this program to identify and implement policy decisions and identify topics and implement the policies from those topics. This includes the Health Care Authority for the Uniform Medical Plan and for Apple Health Medicaid. The Department of Labor and Industries and Department of Corrections is using decisions from this program. State agencies implement the determinations from the HTCC within their existing statutory frameworks, each agency has a different set of laws and rules that they have to follow.

So the purpose of the program 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 these agencies that are purchasing healthcare that the program develops scientific evidence-based reports on medical devices, procedures, and tests and brings them to the health technology clinical committee and out staff supports the HTCC to make these determinations for the topics that have been selected based on the available evidence. So this is a high level view of the entire process from topic selection on through to implementation. The director, the Health Care Authority selects technologies for review and re-review. We have contracted vendors that produce systematic reviews or technology assessments for each topic. The clinical committee then deliberates and makes coverage determinations based on input from the report from public comment from the state agencies in public meetings. And then the agencies implement. This is a process that takes in excess of a year from the time of topic selection to conclusion. So for the meetings themselves, we have these components. Participating agencies present information on the technology and the agency experience and their recommendations to the clinical committee. We then have scheduled and open public comment at the public meeting for the topic. There is then an evidence report presentation from the contracted vendor. The committee then has a question and answer period with the contractor and state agencies and sometimes with the public. There is then committee discussion, development of draft determinations. And a committee vote and that results in a draft decision. So this is the composition of our agenda for. For each meeting for each topic. So there's multiple ways to participate. You can sign up with to receive HTA program notifications by email through our GovDelivery system. Anybody can provide comment when topics are proposed or selected or on draft key questions and on draft and final evidence reports and then finally on the draft decisions. Anyone's welcome to attend the HTTC to public HTTC

public meetings. And present comments directly to the committee. And anyone may nominate a technology for review or rereview. So upcoming meetings, following today in June, there is a topic meeting for whole genome sequencing. That is in the final evidence report stage. In September, treatment for chondral defects is the topic that's scheduled and it is in the final key question phase. So committee members, we look to see if there were draft key questions available for you to look at today. We don't have any draft key question periods right now, but we do have these final key question period for September and November and now would be an opportune time if you have concerns about the scope of these reports to look at those and when the draft evidence report comes out for these topic, there is opportunity for comment from anybody, including committee members. And then we are tentatively working on an HTTC retreat meeting in January.

So today's agenda, we really have 4 things we're trying to do today. We have the previous meeting business we'll review the minutes from February and ask for your approval. We'll then have a brief discussion about the stereo tactic body radiation treatment renal cancer final vote we ran into a question there about a quorum for voting, which we've resolved. And then, we'll have the technology review continuation for spinal cord stimulation and the phase that we're in is the committee discussion and draft decision making process. Once we complete the spinal cord stimulation, we'll move on to bariatric surgery and the start of that topic. So a quick summary since there has been some question about how we got through to 3 meetings for one topic, which is a relative anomaly. We've had 2 topics, 2 meetings before, but we were stretching into a 3rd meeting here. So in November, I'll just quickly review the steps that the committee has gone through this far on this topic. So at the November public meeting, there were presentations from the participating agencies on the technology, their experience and the recommendations. We have the scheduled and open public comment period. We had the evidence report from the vendor. The HTCC began its decision making process at that point on committee questions and answers. There was committee discussion and you began to work on draft determinations, but time ran out for that and you adjourned prior to finishing that. The chair and the committee asked the participating agencies to bring more detailed draft criteria to the next meeting. We scheduled that meeting for February 16th. At that meeting we resumed with a recap of the evidence since some time had passed since the meeting from the evidence vendor with clarification based on some questions that had occurred in the previous meeting. The participating agencies following request from the committee presented more detailed draft coverage criteria for consideration by the committee. And then you resumed your decision process. So this is the committee discussion and development of draft determination phase and that's where most of the time was spent at the February meeting. You discussed the evidence you reviewed your previous evidence votes which are non-binding, those are not final votes. You reviewed the detailed coverage criteria and discussed that and we're in that process when time again ran out for that meeting. You adjourned prior to completing and drafting and editing those criteria. So there was no final vote on a draft determination at that meeting. So that brings us to today or in the decision making process for the committee, the development of draft determination. And, hopefully a committee vote on that draft determination. After

today's meeting, there are publications to our web pages. So we published the approved minutes. We publish meeting transcripts. We will publish any final determination, for example, for the SBRT topic. That will be final, hopefully after a discussion this morning. And for topics addressed in the previous meeting business that's the one And then for any draft determinations and there's the potential for 2 today, that would be a draft determination for spinal cord stimulation and a draft determination for bariatric surgery. So for those draft determinations, there is the comment period for 2 weeks which we will publish those determinations and then, collect comments on that for 2 weeks. So there is a public comment session today for bariatric surgery. Time is available for day of sign up. So don't believe we had anybody sign up in advance, but Val can confirm that for us.

Val Hamann — That's correct.

Josh Morse — Yeah, we'll use the hand raise function to indicate to ask people to indicate at that time if they'd like to provide comments. And we'll keep that open for 5 min. Attendees who are, if we don't have scheduled comments, we'll skip that one. We ask commenters to limit their time to that allotted. And we elevate people to the presenter mode to do that so you'll be your, your zoom status will change there for a few minutes. We ask anybody who's providing comment to please clearly state your name for the record and declare any conflicts of interest. This, we will use the site again for the public comment period. Again, to limit comments to be a lot of time. Are there questions for me about the information in today's presentation from the committee?

Sheila Rege — Josh, are we for the public comment? Are we tied into a certain time that the committee needs to be aware of in case somebody is, you know, planning to come in for that, for bariatric.

Josh Morse — We will monitor for that. Yes, we do have that.

Sheila Rege — I remember the agenda I was there, I could pull it up. But just so I can.

Josh Morse — Yeah, we'll consult the agenda on that 11:05 is the time scheduled. Yeah. Good question.

Sheila Rege — We can make sure that we break. 11:05. Okay. So we'll just have to keep track of that. Okay. Thank you.

Josh Morse — Thank you.

Sheila Rege — That was very comprehensive. Any questions from the committee? If not, then, we will move on to. Let's project the agenda. We have to do the renal first, I believe.

Josh Morse — We do.

Sheila Rege — And I'm gonna hand that over to Janna to chair.

Janna Friedly — I think 1st we need to review minutes. Improvement.

Washington State Health Care Authority

Sheila Rege	That's a good one. Let's review the minutes. Let's project the minutes.
Josh Morse	It's 2 clicks to share. Keep stopping at one. Apologies.
Sheila Rege	And this is the February 16th meeting?
Josh Morse	These are the draft minutes from February 16th And if I can get to the part behind it, I will shrink it. There we go.
Sheila Rege	And we should have looked at this prior to our meeting. Does anybody need any time? Can we go ahead and I'll accept a motion to vote to accept?
Janna Friedly	Motion to approve.
Laurie Mischley	You second it, Laurie.
Sheila Rege	No discussion. On favor, say I.
Clint Daniels	I.
Janna Friedly	I.
Tony Yen	I.
Jonathan Sham	I.
Conor Kleweno	I.
Sheila Rege	And it's just to let everybody know the new voting is only for bariatric. And so, for the renal and for the spinal cord stimulation, we are going to keep the current voting since we're, you know, multiple meetings into it. I will now hand it over to Janna.
Janna Friedly	Right. Josh, do we have something to project for the.
Josh Morse	We do. Yeah, but before we move on from that, I just wanna. The part of what we need to talk about is in the minutes here related to the stereotactic body radiation treatment. So at the last meeting, there was a formal vote in this decision. Stereotactic body radiation therapy for renal cancer findings and decision. You can see here on the projected minutes. 5 committee members voted on the draft for SBRT for real cancer, for finding renal cancer findings and decision. We could not confirm the decision and we decided we would vote on it today's meeting and the pause we need to take here is that we had not had an experience before where we had fewer members than equals a quorum voting on an action. Having not had that experience, we were not familiar with, what typical rules are in a in a meeting we consulted with our attorneys, assistant attorney general about this. And. We do not need to have, for example, 7 members.

	Voting on a decision to make it final. What we need to have is a majority of those who are composing a quorum voting on something. So. This can get complicated quickly if I don't speak clearly. So for example, this was a, this was technically a final decision. We had 5 members present who voted to affirm this decision. We had I think 3 members who abstained. We had a quorum. A majority of those present voted to finalize this. So we do need a quorum to conduct a meeting. We do not need a quorum of those same individuals voting on a decision. So, going forward, we will include that in the committee bylaws. We will work on that for the next retreat to update bylaw and now that we understand the typical expectations of a committee on a vote like this, we will follow that rule. Do you have questions about that? And then we can ask, I can ask the question about whether you want to re vote on this or accept the decision of these 5 members from February. Okay, no questions. So the choice, Janna, I think is yours as far as a revote goes and we can do that right now.
Janna Friedly	Yeah, I'm okay without a revote for this one.
Josh Morse	Okay.
Janna Friedly	And if anyone, I'll just open it up if anyone disagrees with that. Let me know. But otherwise we can accept that.
Josh Morse	Okay, sounds like we're good. Thank you.
Janna Friedly	Yes.
Sheila Rege	You probably should do, so it's. Do you need a motion and a formal somebody to introduce a motion and a second for that?
Josh Morse	Yeah, let's do a motion in a second to accept the previous vote. I think that would seal the deal.
Jonathan Sham	And motion to accept the previous vote.
Laurie Mischley	I second it.
Josh Morse	Val, can you do a roll call?
Val Hamann	Yes. Clint Daniels.
Clint Daniels	Am I just saying I accept that motion?
Josh Morse	Yes.
Clint Daniels	Yeah, accept it.
Val Hamann	Janna Friedly.
Janna Friedly	Accept.

Val Hamann	Chris Hearne.
Chris Hearne	Accept.
Val Hamann	Conor Kleweno
Conor Kleweno	Accept.
Val Hamann	Christoph Lee.
Christoph Lee	Accept.
Val Hamann	Laurie Mischley.
Laurie Mischley	Accept.
Val Hamann	Sheila Rege.
Sheila Rege	Accept the motion.
Val Hamann	Jonathan Sham.
Jonathan Sham	I made the motion, yes.
Val Hamann	Oh yeah, Tony Yen.
Tony Yen	Accept.
Val Hamann	Okay, we're good to go.
Josh Morse	Thank you. Okay.
Sheila Rege	Thank you, Janna. Now we will move on to spinal cord stimulation. Right on time too, this is great. So, I think Josh has actually helped me with the recap in terms of what we have done and what we have to do. Josh, can you project the slide on that you had shown us on the process so right now we're just gonna discuss what? We're gonna start where we left off and for that, there is no public comment on this topic today. We have a summary from the medical director that was in the packet that everybody was encouraged to look at. And let us start with, Josh, if you could summarize where we left off last time on February 16th.
Josh Morse	I can and so I will switch and we will project the draft that you were viewing at that time which has not we have not edited since then, so let me find it. Let's go. Okay, so 2 clicks. In February, you were last, you were discussing exclusion criteria. These are the draft

criteria that the agencies brought back to you for the February meeting. And this is where you were, this is where the conversation was.

Sheila Rege — Right, so to summarize. We had those 3 categories for back pain, peripheral diabetic neuropathy and complex regional pain syndrome we took them separately lots of discussion and now this is where we are. In terms of we came up with cover with conditions And, we have drafted this criteria in terms of pain scale, functional disability, psychologic evaluation, conservative medical management definition of that and the 7 to 14 day trial. Go ahead.

Janna Friedly — I'm sorry. Can, can I ask us to back up? And just review what our straw poll votes were as a reminder.

Sheila Rege — Okay.

Josh Morse — Yes. Let me navigate to that.

Janna Friedly — And it would be helpful to see them by each, each topic. And part of the reason that I'm asking for this is that when you're thinking about coverage criteria, each of the different conditions I think will have different criteria. And so looking at it altogether, is a little bit confusing.

Sheila Rege — That's a good point.

Josh Morse — Okay. Just have to clear a couple of windows here. Apologies. There we go. Okay, here we go. So I think we have a tab for each. For the voting are you asking for the voting on the evidence? Janna.

Sheila Rege — Let's go through the whole straw poll. So. Go ahead and summarize what this was, Josh for us.

Josh Morse — So this was the vote on for failed back surgery syndrome. When you voted on the evidence for safety. Majority of people voted that there was some moderate risk and then the high in the medium indicate you have high confidence. Or medium confidence. That there is moderate risk. To this procedure when used for failed back surgery syndrome. For efficacy, there was, there were 5 votes for, that it was equivocal to comparators. But there was low confidence in the evidence and then there were 5 votes that it was more effective in some cases and 4 cited low confidence in that conclusion from the evidence and 1 sighted medium confidence that it was more effective. And then for cost effectiveness, there was low confidence in majority that it was, equally cost-effective to alternatives. And 2 had low confidence that it was less cost-effective. That's the summary of what those votes mean. These are what we call straw poll or non-binding vote. These are non-binding. These are aren't conclusions. This is taking your assessment for how you as a committee view the evidence. And then for painful or peripheral diabetic neuropathy there was, everyone voted that there was

moderate risk. And the majority said medium confidence in that conclusion from the evidence one had low confidence one had high confidence. Then for the efficacy for that condition, 3 voted that it was equally effective with low confidence. We had 2 people at the February meeting who shifted. Is there a question?

Janna Friedly — No, I.

Josh Morse — 2 people that shifted. That's what the highlight means here. And this was made in the last meeting. The majority voted that there was evidence that it was more effective. Most said low confidence in that conclusion. 1 said medium confidence. And then for cost effectiveness most concluded that the evidence showed it was equal. In cost effectiveness with low confidence, there was one vote for more cost-effective with low confidence, one vote for less cost-effective, and then for chronic regional pain syndrome. Again, moderate risk with medium confidence for the majority with 2 saying, they had high confidence about moderate risk. As far as efficacy, equivocal for the majority with low confidence 3 finding that it was potentially more efficacious with low confidence. Some cases and then cost effectiveness the majority said equivocal with low confidence, 1 citing medium confidence and one with low confidence that it was in the evidence that it was less cost-effective. And then you, you had, I don't have a record of. Yeah. So you did straw voting and again you do the straw voting. I'll use an example. If you know from this straw voting, that the evidence in the committee are not supporting coverage for something. Then that does not, that means you typically don't have to go to developing conditions for coverage. So the straw voting to get to this point indicates tells you as a committee that okay, we may be covering this with conditions, we need to know what those conditions are to vote. And that's what you did at the previous meeting and this is how those results looked. You, you did this vote in originally in November. You took your temperature as far as where the committee was sitting. The yellow indicates one, moved their vote in February from the previous meeting, but this with indicate you have a reason to develop conditions to, to then contemplate for a final vote. And historically what you've done is you've developed your conditions. And then you, vote as a committee. And if the conditions are acceptable to the majority, then you would have a conclusion of a vote of covered with conditions. But if you can't come to agreement uncovered, unconditional coverage your result could be not covered still or it could be covered unconditionally because you still have to take that vote as that'll be your final vote, hopefully today. Is that was pretty comprehensive? Hopefully that's what you wanted.

Sheila Rege — That was very helpful and refreshing all our memories. Any discussion at this time? So we can go ahead.

Janna Friedly — Yeah. No, I just said thank you.

Sheila Rege — So we can go back to the draft language we were crafting.

Janna Friedly — Conor has a question.

Conor Kleweno	Just a question on, once we get to the discussion of covered with conditions, given that we don't have, have to have a unanimous decision on coverage for it to pass. I'm assuming that applies to the covered with conditions? It'll it almost seem like we had to have a unanimous decision on the conditions, but if somebody is always gonna vote no, no matter what then it sort of makes it impossible to have a unanimous agreement on what conditions it would be covered, but I just wanted to have that clarify for us when we get to that.
Josh Morse	Yeah, no, that you, you rarely have. Like a 9 or an 11 to 0 vote on your conclusions. So no, you don't have to have. 100 consensus you're seeking a majority so.
Sheila Rege	And it's a simple majority, correct Josh? It's not a.
Josh Morse	It's, yeah, it's a majority. I don't know.
Sheila Rege	Yeah, so it's not, not a you know, you don't have to have 3 quarters or majority.
Josh Morse	No, yeah, simple, right. More than half.
Sheila Rege	Did that ask the question, Conor? And we have had some decisions in the past where it's been. One vote that made the difference. Any other questions? There's no objections, we can go back to the draft language and now the process will be will draft this language and then we vote again, tis will be the final vote on accepting the draft language cover with conditions or not. Or and Conor response to what you're saying if they are some people who still feel that. They would not cover, then they would vote against this. Is that, was that your question?
Conor Kleweno	Yeah, basically, cause it, you know, the thought was or the interpretation I had was, okay, we have to have a majority vote for coverage. And then we're gonna have some sort of discussion of the conditions, but just wanted to make sure that we weren't saying we had to have a unanimous agreement on the conditions because sometimes I think we get bogged down on that. And we still just need a majority of vote on the conditions.
Josh Morse	Right, yeah. And if I can say what you both said in a slightly different way, your final decision is a vote on the draft is a vote of cover, cover with conditions, or not cover. Before you can get to that vote, you need to know what those conditions are. So you have not yet voted to cover, cover with conditions or not cover. That comes at the end after you have agreed on. Yeah, if we're going to do conditional coverage, these are the conditions. So that's why you do the straw voting to figure out are we headed for. Potentially for conditional coverage or not. Once you've developed your potential conditional coverage, then you do your final vote of cover, not cover or cover with conditions. Does that make sense?

Conor Kleweno	Yeah, it does. I just sort of in the past, I've observed that we sometimes get bogged down on some of the wording and the conditions when in reality we just need a majority vote on it and can continue to move along. So.
Josh Morse	Right. And often that vote like somebody will vote not cover and you know, and 7 people will vote cover with conditions. And one person might vote unconditional coverage, coverage with no conditions. And then there is the comment period after this, right? So there is one more opportunity. And that opportunity is if there's evidence missed or if there's something unclear. About the intent in the language that we put out after this.
Jonathan Sham	Can I ask Josh? And I'm sorry, I don't wanna get bogged down in the process, but I think it's probably important. So for example, if I just don't wanna cover at all and vote, no coverage on this particular draft. That's added to someone who wants to cover with conditions but with, with different conditions it would seem that that could derail a majority of people who vote to covered with conditions. Does that make sense? So some people might vote yes on a draft, some people might vote no. And some people might both know just to specific wording that they want different conditions, but they still want it covered. And so I just wanna make sure I understand how that gets resolved. Because if I say no to this for a different reason than someone else, it can add up to a global no.
Josh Morse	Right.
Jonathan Sham	If that makes sense?
Josh Morse	Yeah, no, I think that makes sense. And that's what you is. I mean, you do need to come to consensus, hopefully on, on these conditions that you'll then, you know, are the, would these be acceptable? To consider for that final vote if that makes sense yeah there is the potential to, to not, I mean, hopefully not, but there's that potential that you can't come up with agreeable conditions. I don't know what that means. For, for example, for a majority, right.
Jonathan Sham	Great, that's helpful to make sure we're on the same page.
Tony Yen	Josh, can you just share my personal approach to what Jonathan just mentioned?
Josh Morse	Sure, please.
Tony Yen	So, I'm leaning towards not covering, but I'm looking at these covering with conditions in the spirit of if I were to cover this with conditions if I wanted to, what were the conditions that I think would be rational and reasonable?
Jonathan Sham	And I think that's a totally reasonable approach, Tony. I just wanna make sure that, you know, I guess by letter of the law, you might not have to take that approach. You could just say don't cover and be done with it. Yes, you have to handle that on a case by case basis.

Washington State Health Care Authority

Tony Yen	Yeah, I got it.
Sheila Rege	That's, let's go on though. And let's, I wanna move us forward. We can think of the theoreticals. But let's kinda look at the language. So we know what we're deciding to either, you know, cover public conditions or not cover, cover unconditionally or not, all 3 choices. So is everybody comfortable you have this to look at it, do we need to add anything to this? But the those criteria and we had done this for all 3.
Janna Friedly	Yeah, so Sheila, I'm really struggling with combining all of these in one in one document because they're 3 completely different conditions. And so we haven't in this defined what failed back surgery syndrome is for example, and we, the ODI is a back pain specific questionnaires not used for peripheral neuropathy or CRPS. And so some of the, so we're, sort of conflating.
Sheila Rege	Okay.
Janna Friedly	Different conditions and criteria. So I think you have to, in my opinion, you have to separate those out and have different, different criteria for each of those conditions. And that's consistent with the if you're using the evidence to guide, you know, you have to use the, some of the criteria that were used in, in the studies, for those, if that makes sense.
Sheila Rege	Yeah, that is, yeah, that's a request and if nobody has an objection to that, we could, and Conor, I see your hand up. Oh, we could do that and we could, Josh, we could just say. This is for fail. The lower back pain the FDSS and then we'll take it for chronic regional pain syndrome, for painful diabetic neuropathy, Oh, go ahead and look at changing it based on the evidence. Conor, were you speaking on this or you speaking on something else?
Conor Kleweno	Something else, but I do agree with what Janna said.
Sheila Rege	Okay, so in without any more objections, we could do that and we keep that because at least we have a template and we could either add or I don't want to start over. So this would just be for failed back surgery syndrome.
Josh Morse	Yeah, so I'm just gonna create a couple of copies of that change the view or the review here to. No markup. And let's make this bigger. Okay, so you wanna start on with failed back surgery syndrome?
Janna Friedly	And sorry, one more clarification. Is that including chronic low back pain? Cause that those are 2 separate things too in terms of diagnosis.
Sheila Rege	I was muted. It would just be for failed back. So FBSS, I think what Josh is doing, Janna, is. He's separating it. Josh, if you're here.

Christopher Chen	Hey Janna, can I clarify this Chris. Were you thinking that the exclusion criteria would also need to be conditioned specific? Cause I just noticed Josh, you, we're only copy paste and the proposed criteria by condition.
Josh Morse	Yup, I didn't copy that yet.
Christopher Chen	Okay.
Janna Friedly	Yeah, I mean, I think, you know, there's gonna be a fair amount of overlap, but there are some specific things. So it just, in my mind, it just gets confusing to sort out in here which things are specific to which condition. Okay.
Sheila Rege	Right.
Josh Morse	So, Janna, I think, or do you want to work on these criteria here for failed back surgery syndrome and then repeat that for 2 or 3 other conditions?
Janna Friedly	I think we have to. Right?
Josh Morse	Okay. And this is, is this what you need in this window then right now?
Sheila Rege	If you, if you just bold or underlying that this is just proposed criteria FBSS. And then we'll have proposed exclusion criteria. Okay. So let's just work, we're taking a 1 at a time, FBSS. Conor, do you wanna speak now or?
Conor Kleweno	Sure. Cause my question I think is generalizable to the different conditions. I just had a clarification question related to costs for the percutaneous trial. And I don't know if this is a question for the expert and or the agency, you know, I, I don't have any experience with this procedure. But I am a sub-specialist, for procedures for my own. So I have, I do a procedure on a patient. And if professional fee will drop and a facility fee will drop and that will get billed out to someone. And so I'm trying to understand if a provider does a percutaneous spinal cord stimulation for 2 weeks and it doesn't work, I'm assuming there's still some sort of charges related to that. So are we saying that we're gonna pay for the trial, but if it and if it doesn't work, we're not gonna pay for any continuation or we will pay for additional services if that trial is successful. And I apologize if this is not, that doesn't quite make sense, but from, you know, as a surgeon myself, this is how I understand what costs and charges are incurred. There's you know ENM services there's you know provider fees for the procedure and there's facility fees that are incurred or charges that are occurred for part of this. So I just was as I consider cost of these. I wanted to understand how that would play out for, what we're proposing for a trial period. And obviously I'm not asking the exact dollars, I'm just saying in general, how that, logistically would work. So a provider sees a patient and thinks that they are indicated for this. They do a trial and are we saying that they're gonna do it for free? Because it's not gonna be covered or that we're gonna cover this trial or how that works.

Sheila Rege	Josh was the, was, was that in the scope, whether the file was covered or not or was it all locked together?
Josh Morse	I think the trial is a, I will defer to the clinical expert on this, but my understanding, the trial is a requisite part of this process. And I assume it's part of the cost of the whole procedure. I don't know about the separately payable. I don't, I assume it's not free, but I don't know. I don't know if Dr. Strunk has that.
Joseph Strunk	So they represent 2 distinct procedures. And so there are charges for both of those procedures. I can't speak with any more affinity about pricing and things like that. But it represents 2 specific events and 2 separate billable processes.
Conor Kleweno	Are, are you saying the percutaneous is one and then a separate one would be the definitive one?
Joseph Strunk	The implant, which is only performed if a successful trial occurs.
Conor Kleweno	Yeah, okay. Great. That's the way I understood the logistics of it. What I didn't understand is who's paying for what when in terms of our discussion.
Jonathan Sham	So I totally hear what you're saying, Conor, as you know, as a fellow surgeon, I, give you this thing. So I guess what I would propose to address that. Because it is part and partial to the overall coverage determination. Would just be. If all of the proposed criteria for coverage, including exclusion or met, then we would support the trial then of course if the trial is successful we would then support coverage for the ultimate procedure. So I don't know if that's be written out specifically, but it would seem like that's the most specific, the most it's most straightforward and way to cover and consistent with what we all understand the process to be.
Conor Kleweno	I think, think that makes a lot of sense, Jonathan, and happy to hear what other people think, but you, cause you could see if, we don't specify that, then every single person that walks in, we trial it with no impunity. I'm again, I'm not making, trying to make a pejorative statements. I'm just playing out from a cost perspective one way to understand that is have some sort of criteria for the trial period and I give what you're saying to meet the other criteria prior to the trial period. Is that what you were saying, Jonathan?
Jonathan Sham	Correct.
Sheila Rege	That's a good point. So Dr. Chen has his hand up.
Christopher Chen	I just want to just check in here. Typically the payment methodology, is out of the scope of the committee's decision and that's part of our implementation process. And, I though, so I think, my suggestion based on like looking at other kind of payer coverage approaches would be for the committee and of course I defer to the chair, Dr. Rege and Josh, your guys guidance on this, but I think, would consider, you know,

	if, the procedure is covered, then I would consider the trial and the procedure together, right? And so not, for example, landing on a decision where you covered the trial but not the procedure or trying to tease those apart too much, because the way that other payers have covered it is you know, making these broad criteria lead the providers to understand in what circumstances the procedure would be covered and then the kind of the, the results of the trial being that last criteria kind of is where that slots in. And then, and would also just recommend not trying to get too much into the specifics of the reimbursement on the, the trial versus the procedure because that's not part of evidence reviews, it's not part of like the cost effectiveness studies. The committee charges to focus on the evidence and the details like coding billing procedure etc. kind of follows this part of our typical implementation process but yeah I don't know Dr. Rege and Josh if that is the right
Sheila Rege	So Dr. Chen, what I think, is being asked of the committee is that for somebody to be eligible to do the trial of for stimulation, they have to meet the neuropathic pain, disability criteria, psychologic evaluation, and 12 months conservative therapy. That was just a clarification. That, a person couldn't come in and on day one have a trial just because they have failed back surgery syndrome.. So if you think the agency doesn't need that, that our discussion today outlines kind of the committees thinking then, we're good.
Josh Morse	Yeah, I think it's a great question. I think we can, I agree with Dr. Chen. I don't know that I've seen criteria like that. I think you could easily add a bullet here or we could add it after that says, patients must meet above criteria for the trial to be covered and then patient underwent trial of your specifications after that. Good question though.
Sheila Rege	That's good question. I have 2 hands up. I think Janna was 1st and then Christoph, I think you were after Janna.
Janna Friedly	Yeah, so I think that makes sense to me. I think what I do, struggle with a little bit is the concept that you don't include that cost of the trial in thinking about cost effectiveness and the impact of this procedure. So thinking about what I guess that one question is what percentage of trials, our negative trials. Meaning how many how many patients have a trial of you know 5 to 14 days 7 to 14 days and then don't go on to, to, get a permanent, and shouldn't that caught because those, are going to need to be reimbursed. And shouldn't that cost be included in thinking about the overall cost and cost effectiveness of this procedure. So if you have if you do a hundred trials, 5 patients who will ultimately go on to a spinal cord, that's a that's a pretty different than you know 95% of the time that these are positive trials. So I'm struggling a little bit with it with not considering that as part of this.
Joseph Strunk	I think, if we reference the studies that you, that we've kind of been reviewing the, those well designed and selected patients that's that conversion to implant is something in the order of 70 to 90% go on to implant.

Sheila Rege — Would, I'm gonna parse out the 1st question, which was, meets above criteria prior to percutaneous trial. Is everybody comfortable with that being added in? Is there any objections to that? To reflect what the discussion was. And Dr. Chen, I will also ask you if that's in the scope of what you need from the committee?

Christopher Chen — And, and I think like this is could be a helpful addition to provide clarity, yeah, totally defer to the committee for determination of what, what, what you all would like for criteria, but, it, does seem like it helps address some of the questions.

Sheila Rege — Dr. Lee.

Christoph Lee — Yeah, I guess I have somewhat related comment, but also a separate question. If you, if you make it that the patient needs to meet the above criteria prior to a trial, 12 months of conservative medical management seems like a really long time to wait. Like if someone's in really bad back pain. Right? And you're asking them to go through physical therapy, CBT, find other conservative management techniques. It's a lot of work on their part and it could be out-of-pocket expenses for them if things like acupuncture, chiropractic, are not covered, right? And so you're asking them to do some management and all these are ands, and that's a lot of ands. They may not have access to CBT. They may not have access to acupuncture or chiropractic. It just seems like you're asking them to go through a lot of hoops to get to this point for something that maybe for that individual more effective than acupuncture or chiropractic services. In addition, some of these conservative managements that are listed I haven't seen the evidence that they're more effective. So I'm not sure how at least the last bullet point for the conservative medical management made it in here. And so like, you know, I think there was a comment at least in the notes that I read from the last meeting in February that question the 12 month period. And I guess my question for the conservative medical management piece of it before I'm going to perky nation trials if patients actually have access to this. And if these are covered services. And if these are effective services. I, my preference would be that these are ors.

Sheila Rege — So.

Christoph Lee — If you're gonna leave a 12 month waiting period on it.

Sheila Rege — Can somebody, speak to what the trials had said on that? I do remember a significant time for conservative medical management. And, and remember, we, our charges to look at what the trials had and not come up with our own personal that a patient can't afford it so we need to do it. We have to be guided by our North Star, which is the evidence presented. Dr. I see. Is anybody wanting to speak on this? Dr. Friedly? Okay, go ahead.

Janna Friedly — Well, I'll just, comment. I do think that the 12 months was part of many, many of the studies and the definition of conservative medical management is across the board challenging and most people don't really know what that means and so it is difficult to come up with a criteria. So I understand the concern there, but I do think that there

has to be some, some attempt to use less costly and invasive procedures before, before this. If we're thinking specifically about failed back surgery syndrome, I think we haven't gotten to the point where we can specifically comment on, on that because we 1st have to define what is failed back surgery syndrome, which is kind of, an elusive term to begin with. And I think by definition when you when you consider failed back surgery it's a, you know, consider failed back surgery it's a you know at least you know the least you know 6 to 12 months post you know, at least, you know, 6 to 12 months post, post-surgery. So where's that 12, 12 month, period. But I do think it's reasonable to include, some amount of conservative medical management and many of these do have, some evidence for them, but I think it's, it's challenging. I don't know what the right answer is, but I think we need to include some.

Sheila Rege — I have, I think Clint Daniels, looking at your hand up.

Clint Daniels — Thanks. 1st I just want to pair up with Janna just said and then also there was some question about the 3rd bullet. Both of those are guideline recommended treatments for chronic low back pain, same as physical therapy and CBT. So those, those 2 therapies are not shown to be superior to the 3rd bullet. And then as far as FBSS, with any of those treatments, there's so a lot we're very much in the infancy. I think of. Understand the best conservative approaches. I'm in favor of and I think this is we're talking about a pretty invasive long-term treatment. I don't think 12 months is that long when it comes to chronic back pain. And, I think all of those are much safer alternatives that should be trialed first.

Sheila Rege — Thank you. I think Conor.

Conor Kleweno — Yeah, just kind of maybe echoing the last couple of comments. I definitely appreciate, it was Tony's concerns on it about the patient with the, you know, severe pain and waiting a long time, but we're really, sort of discussing my impression is more chronic situations, not in, a not an acute setting where we're gonna make somebody just wait, just because, but we have a, diagnosis or disorder where we have a chronic situation that we're dealing with. And so, you know, obviously I don't have the magic number of months that's appropriate. We have to go by based on what the evidence shows. But that's the way I had sort of wrapped my head around why the long period of waste because we were already in a long period of evaluation and management by the time the patient was probably going to be at these providers.

Sheila Rege — Laurie?

Laurie Mischley — Yeah, can I just clarify if someone had done PT and CBT prior to their 1st back surgery in the 1st place. Is this 12 months of conservative therapy after the back surgery or what if they had done this for their chronic low back pain prior to their 1st surgery? Another 12, you know, where does the clock start?

Clint Daniels — I have assumed it started after the surgery.

Sheila Rege	That was assumption.
Laurie Mischley	But they're, they're. Yeah.
Sheila Rege	Does, Clint, do you want to take a vote of the committee or? I think you brought up the or. Or are you comfortable with, with moving on, what would you like to to get past this?
Clint Daniels	I think you said Clint, but I think you might have meant Christoph.
Sheila Rege	I might push off. I'm sorry I'm not thinking. Yeah, you're there right in front of me on this. I've got 2 monitors and Yeah, it was Christoph. Sorry.
Christoph Lee	Yeah, I think the explanations I received made sense to me. Not being in the low back pain space. So if everyone's comfortable with the and. I can move forward with that. I do, you know, I do wonder about the 12 month period after surgery, as Laurie was pointing out if these didn't work for that patient before the surgery. Are we saying that's gonna somehow work after the surgery now?
Sheila Rege	No offense to my surgeons, but they do do they do get in that space and the cost start to issue and stuff. So I think it's a different. This is how I look at it. Laurie, is that your hands still up?
Laurie Mischley	Yeah, yeah, no, I just another point of clarification with this and or, or I just want to make sure that I do think it is excessive to say 12 months of PT and 12 months of CBT and 12 months of acupuncture. I think what we are trying to say is over the last 12 months you have given you have participated in all of these things you've attempted and so. Just I think we should be a little more explicit about what we're asking for here.
Sheila Rege	So you're saying in the 12 months of conservative, the full course of physical therapy or cognitive behavioral therapy or conservative management.
Laurie Mischley	Not, you pick one of those, but all of these things need to be tried in for 12 months. You know, over I guess I just don't think it's I don't think it's realistic to ask.
Sheila Rege	Okay.
Laurie Mischley	Everybody to do 12 months of all of those things.
Sheila Rege	Like a combination.
Clint Daniels	Yeah, not 12 months each. Just once.
Laurie Mischley	Right, right, exactly. Right. And.
Sheila Rege	A combination. I am gonna propose something. If we could, Josh, you're not gonna like this, I would propose a 5 min break. I wanna pull the studies myself. And you know, I

	just don't wanna. Go on, I try to and I need 5 min of not looking at a camera, but before that, Janna, go ahead.
Janna Friedly	Well, I, I was just gonna, I agree about the, 12, it's, 12 months of a combination of those things, not all of them are necessarily 12 months of physical therapy, for example.
Sheila Rege	Right.
Janna Friedly	But I do think 12 months after a surgery is a very reasonable, time period that if, if you suggest that you should, you should move on to spinal cord stimulator 3 months after a major back surgery. That's not giving it enough time, you know, to allow recovery and to really see what's going. So I strongly believe that, that we should include 12 months after surgery
Sheila Rege	Yeah, I, I know we got Jonathan, I'm going to take your question and then I'm going to do the chair prerogative of 5 min break. I just want to look at the one of the trials just to make sure we're not, misunderstanding, but I do like that combination. And Josh, if you will work on something, language there to say that's the what the committee wants, not 12 months, and cognitive and.
Josh Morse	Yeah, I understand the intent.
Jonathan Sham	Okay. I was gonna give some proposed, I was here some proposed language Josh if that's helpful.
Josh Morse	Yeah, please.
Jonathan Sham	I was gonna propose language of 12 months conservative medical management in total, comprised of and then to take out defined as I think that captured what we're all thinking and saying. But we can all of them.
Sheila Rege	I think it does. That's a good idea. Janna, you will just, I'm gonna get off camera. I'm gonna try and put one of the studies. I just make sure we're not excessive. If you will just take over 5 min and continue.
Janna Friedly	Sure. We can, we can keep going. Jonathan, did you have anything else or your hand is still raised or?Do you have another comment?
Jonathan Sham	Just haven’t lowered it, sorry.
Janna Friedly	Okay, and then Conor.
Conor Kleweno	Yeah, just kinda back to your point, right, right now we're discussing FBSS the diagnosis of which I also find somewhat elusive, but let's say that that's what we're discussing right now and that helps me wrap my head around more of the 12 month post-

surgery. As opposed to say we are describing a diagnosis of lumbar arthritis, lumber spine arthritis. And that's why I think that the post operative time period as opposed to including like a CBT preoperatively. And separating those 2 situations. If that makes sense.

Janna Friedly — So what would you propose, Conor? Yeah.

Conor Kleweno — No, I'm agreeing with what we're doing and the reason is because we're discussing failed back surgery syndrome or not describe we're not proposing criteria for lumbar arthritis, for example, or some other spinal stenosis.

Janna Friedly — Yeah.

Conor Kleweno — So because we're, you know, been,, you know, tasked with this diagnosis. Those we should consider it a post operative perspective.

Janna Friedly — Does this language, though this language here does not capture that I don't think. 12 months of conservative medical management in total, there's nothing here that says 12, you know, that, it needs to be 12 months post operatively. More that we need to wait 12 months. You need to be at least 12 months.

Conor Kleweno — Oh no, I think.

Janna Friedly — I think maybe that is the definition of failed what is the definition of failed back surgery. We haven't defined that and I think that needs to be defined here and maybe that's a separate criteria to define what failed back surgery syndrome is. I don't.

Clint Daniels — Should that be here to the 1st bullet? .Up above or

Janna Friedly — Yeah. That you need to be at, you know, at least 12 months post-surgery.

Joseph Strunk — So my experience has been that it is fairly elusive to define failed back syndrome or at least it hasn't been, many definitions have been proposed. Some of the more common ones are just going to be persistent, low back with or without leg or limb pain following spine surgery. That's often kind of the encompassing diagnostic criteria.

Janna Friedly — Yes, and I would, I would recommend for this that that we be clear that this is for neuropathic, pain, so not for persistent low back pain, but is, really for the neuropathic component. So I, I mean, neuropathic meaning, leg pain.

Conor Kleweno — Do you think a question for you, Janna and Joe or Joseph, are we defining that appropriately in the next bullet, you know, with our criteria. Is, is that sort of answer our question there at all or sufficiently?

Janna Friedly — Yeah, I think we should include that I think there needs to be some definition on neuropathic pain.

Joseph Strunk	If, if we actually look at the studies though that we're discussing, those were pain that was both in the back and the leg. They're not there have been multiple studies that look at both back and leg and some combination. There are, I agree there are some studies that do look just at leg pain. But especially the studies that look at high frequency stimulation are specifically low back. Neuropathic, yes. It, it often is classified under that pain phenotype. But those 2 are part of the fail back syndrome category.
Janna Friedly	Right, except we have to we have to define back pain and this spinal cord stimulation theoretically is targeting neuropathic pain is not for. It's not for muscular pain. It's not for, you know, so I think when you look at the mechanism of what is proposed to be the mechanism of spinal cord stimulator. I think we have to think about that. I, one of the challenges with the studies is that they used very, often times not well defined criteria for what neuropathic pain is, and so it was, not very clear in, many of the studies. But I would argue that we if you if you do not clearly define that that is going to be very broad.
Josh Morse	I'm moving words around as I listen and learn. So if I'm putting the words in the wrong place, just tell me where you think they're best placed.
Janna Friedly	Yeah, I'm okay with this for now. And the other, the other criteria, you know, looking at the psychological evaluation to rule out substantial mental health disorders. And maybe this is, maybe that's okay as we're to given that you've got cognitive behavioral therapy below, but, but I think the intent and in the studies it's, it's, you know, sort of untreated, psychological conditions or, you know, making sure that people are engaged in treatment for their psychological condition. So maybe it's fine as it's worded, but just wanted to call that up.
Laurie Mischley	I would support adding the word unmanaged or untreated. I mean, we're not saying people who have mental health issues aren't eligible for the procedure.
Janna Friedly	Yeah, I mean, you, you could say, you know, if it's, if it's a criteria, psychological evaluation and appropriate treatment for substantial mental health disorder. And that's a little bit. Okay.
Conor Kleweno	I agree, we're not ruling something out here. We're just, you know, we're saying we want to make sure that if somebody has some, psychosis that's being treated, but if somebody has a previous diagnosis of anxiety or depression, we are not excluding them from access to this treatment. You know, unless it's floridly untreated that is, you know, confounding the situation.
Joseph Strunk	As a point of clarification for me, for the cognitive behavioral therapy is that a covered benefit from most of these patients? If we're gonna be requiring it.

Sheila Rege	I'm back. I'm sorry. I was looking through the trials. I don't know if it is or not, but I don't know if it's in our scope to open up another. Oh.
Josh Morse	As far as I know, it's a covered benefit in the plans in the programs that are addressed here.
Joseph Strunk	Yeah, I just from an equity standpoint wanted to make sure that we weren't asking vulnerable patients to pay for something that they couldn't afford.
Josh Morse	Yep. Nope, CBT, acupuncture and chiropractic are being added to Medicaid effective next January for adults. Acupuncture and chiropractic are currently covered with some limitations by workers compensation. And I think they're both covered in uniform medical plan and same for CBT and all the programs cover physical therapy.
Sheila Rege	So Josh for the future, will you ask?
Christopher Chen	And I also just want to clarify. Oh, and not sorry, I just wanted to clarify that generally for Medicaid there's no cost sharing or copays.
Josh Morse	Thank you.
Sheila Rege	I would recommend though that. Josh, we, we kind of just define our scope of the committee. Because if you know, if there's something in the studies that is being asked for that then we don't go down the rabbit hole of oh is that covered. That's, that's, I don't think that's within our key questions and stuff. So I don't wanna make that out. do not wanna make that a, formality.
Josh Morse	That's a good point. Yeah.
Sheila Rege	I'd like to kind of put some guardrails on what we as a committee are supposed to do. How are we doing on time, Josh? When,
Josh Morse	We have an hour and 15 carved out for, for this conversation and to get to a vote. So we're at 9 15. Our agenda is to move to 10:30. 1045. There's a break. There's a 15 min break.
Sheila Rege	Okay.
Josh Morse	30 before we go into bariatric.
Sheila Rege	Okay. So is everybody comfortable with this for fail back surgery? Any other thoughts before we move on to, did you talk about the exclusion criteria? Let's move on to that exclusion criteria. Any discussion on that?
Conor Kleweno	I'm confused by the second, the last bullet a little bit, maybe in terms of wording that, we may be able to make a little bit better. I'm assuming what we're not saying is if you have arthritis in your hip and you got a total hip replacement, then you're better from

	that you're we're not saying that's an exclusion if you're saying substantial persistent chronic pain in other regions that have that are requiring treatment so we're trying to separate out confounding of an existing ongoing pain syndrome or existing confounding diagnosis is that is that accurate?
Joseph Strunk	I think memory serves from our conversation that was major intent of that line was like you mentioned if someone has a chronic shoulder pain and that is more substantial than their chronic back pain. That probably would be a patient that the utility of a spinal cord stimulator in the grand scheme of their whole pain experience is unlikely to produce significant benefit and was probably not or some other pain syndrome. So their primary pain complaint is not what we're trying to address then that we're probably not addressing the right thing. But I agree with you that I'm not sure what to do in a patient that has a total joint surgery that then does that, does that take them out of this category for a full year?
Sheila Rege	Conor, what was your, what was your?
Conor Kleweno	Yeah, I just think and I think Christoph has a comment, before I speak.
Sheila Rege	Okay. Christoph.
Christoph Lee	I was just gonna say that bullet point seems pretty nuanced and maybe something that the surgeon and physicians managing that patient can make better than us in terms of exclusion. I assume they're gonna go through some exclusion criteria before deciding to put a stimulator in them, including major psychological disorders and chronic pain syndromes and such. So I think.
Conor Kleweno	What if we, oh sorry, go ahead.
Christoph Lee	Yeah, so like I don't know if we should be doing exclusion right here based on clinical scenarios for this coverage decision.
Conor Kleweno	I think for me, changing the tense would help sort of active, substantial chronic pain in other regions currently requiring treatment. I don't know. Janna, I guess you have your hand up. I'll mute myself. Sorry.
Janna Friedly	Yeah, no, that's okay. Yeah, no, I agree. Although I do believe that you need to include this as an exclusion criteria, most of the studies include some sort of vague statement again not well defined but that there's not chronic widespread pain conditions fibromyalgia other, other chronic pain conditions that will make it less likely that this will, be beneficial for people. So, I strongly believe that we need to include something in here. But it's hard to define that.

Christoph Lee	It could be differentiate like chronic pain syndromes from mechanical pain like actual like you know this person has a rotator cuff injury but something. Because I think you're getting at does this person have some type of psychosomatic chronic pain issue and I think that's different from mechanical pain that is causing a lot of pain, but could, you know, undergo surgery in different area.
Conor Kleweno	But even the example, let's say you have horrible hip arthritis and you're limping around and you can't participate in sort of normal healthy activities and things like that. You get your hip replacement, your pain goes away and then your low back symptoms from failed back surgery could improve. Just sort of playing it out. So. I don't think it's unreasonable to make sure if they have a concomitant, potentially confounding pain stimulus. That if it is actively treated and resolved could potentially, help with, their failed back surgery syndrome as well.
Joseph Strunk	If you were to consider just changing it to just more severe pain that may also help. Many of the studies as Dr. Friedly mentioned, we're looking to make sure that they that their primary pain was the pain being addressed and that if they did have other pain it was of a smaller magnitude.
Janna Friedly	I think it's just, it's so hard for people to distinguish and in Conor's example about the, you know, hip arthritis and back pain it's really hard for people to distinguish location of pain and where it is and what's more and less. So I don't know that we can that we can really make that any more clear. I think active, substantial chronic pain. Maybe the best that we can.
Sheila Rege	Does any of the committee members have any heartache with any of these exclusion criteria, given the discussion I think given the discussion this is we're still only on failed back surgery. Remember what we still have others to do. So, and I do want to finish this today.
Conor Kleweno	Sheila, I'll just say since I brought up this point, I'm satisfied with the changes made with this bullet. So.
Sheila Rege	Okay. Josh is there any way to make it all smaller so we can see everything on one page?
Josh Morse	There probably are ways to do that.
Sheila Rege	So we, you know, kind of the committee can look at it and, and then my suggestion would be to work on language. And Janna, you're the one who brought this up, so I'm gonna look to you for help. Look to language now for proposed criteria for peripheral diabetic neuropathy. And then the post criteria for complex regional pain syndrome. Should we work on that prior to doing voting, which, all with members of the company like voting on this and close this. What would members of the committee like? And Janna, since you brought it up separating it, I'm gonna look to you comment first.

Janna Friedly	I don't have a preference to which order.
Sheila Rege	Josh, do you have a preference? Pro procedure standpoint. We could, we could take a book. We could take a, but it's front and center.
Josh Morse	I don't, I don't have a preference. For you.
Sheila Rege	So let's, take a vote.
Janna Friedly	So actually Sheila, sorry, I do have a preference. I think, you know, from our experience sometimes as we're talking about criteria for other conditions, it becomes clear that the work we need to change the wording and then we end up going back and making it consistent with the other with the other conditions. So to avoid doing that, I think probably getting all of them written the way that we want 1st makes sense.
Sheila Rege	Okay. Okay. And when the data was presented, what was the next one? Was that? Peripheral diabetic neuropathy or complex regional pain syndrome.
Josh Morse	What data?
Sheila Rege	Okay, no, and I'm looking at that. I spend that time looking to the experts presentation, sorry. Let's do chronic regional pain syndrome next. And so this would be proposed criteria for.
Josh Morse	There's a few changes I assume we want to carry over here. Do we just want to start with another copy of what we just did? what you just did.
Sheila Rege	Yeah, right. And then we will. Change and I think Clint was the 1st one to have you.
Clint Daniels	Yeah, I was just gonna say, we should remove chiropractic for this one and the neuropathy when we get to it, cause it's not indicated. And then probably ODI related back specific stuff too.
Sheila Rege	Okay. We'll let you address that once we start. That's good ideas to discuss.
Josh Morse	Confusing myself. Let me do. Sorry, I did something wrong. You suggested removing chiropractic. Was there another change?
Clint Daniels	Oswestry Disability Index. Do you know, earlier that's specific to back pain?
Josh Morse	Okay.
Clint Daniels	So it could be removed, the whole line.
Janna Friedly	Yeah, and this is I have to say this is where it gets challenging to come up with criteria when we're not reviewing what are the evidence-based approaches to complex regional pain syndrome that should be tried prior to, to this treatment. Cause there

	are many treatment approaches, but that's not within the scope of what we have reviewed, so it makes it a little bit more difficult to clearly define what that appreciate quote unquote conservative medical management is.
Joseph Strunk	I can speak a little bit to the common practice which would be, would be physical and occupational rehabilitation in medication management and use of sympathetic blocks.
Janna Friedly	Right, but that's why we're not covered, you know, that's where it gets a little tricky.
Joseph Strunk	Yeah. Just this is a point of what.
Janna Friedly	Yeah, I get that I just it's not within the scope of what we've reviewed so it just makes it a little bit more challenging. But I would, I would agree with including occupational therapy as well and, include something about, medication, you know, trials appropriate medication trials as well. EMG or nerve conduction evidence of nerve root impingements not really relevant to complex regional pain syndrome. I would include the Budapest criteria, for diagnosis and make sure that's there, but, it's, we're not really, it's not a nerve root issue.
Josh Morse	Okay, so did you want me, did you wanna add a line here under conservative medical management about medication?
Janna Friedly	I think, you know, if you wanna instead of chiropractic, you know, another modality of conservative, I would include, you know, medication appropriate medication trials. Which is a really vague statement, but I think there are many available treatments that people use.
Josh Morse	Did you wanna add and/or occupational therapy?
Janna Friedly	I would.
Jonathan Sham	To follow up do the AMDs or Joseph or maybe the data of yours just have information on the inclusion, exclusive criteria for the actual studies that we're viewed on CRPS to inform us on this point? It would seem like that would be just kind of a foundational information that would be helpful in crafting these. Cause I'm certainly not an expert on defining this, but If there is specific inclusion criteria in the study that review it, I think.
Joseph Strunk	Yes, CRPS is a very challenging diagnosis and one of which as Dr. Friedly has already mentioned is defined by the Budapest criteria. Which includes severe pain without other known source and simply referencing those will put you in line with the studies that use that exact criteria to enroll their patients.
Jonathan Sham	Is that a numerical score or is that just?
Joseph Strunk	It is a, it's a combination of several things. It is not a numerical score. You're looking for signs and symptoms in 4 different domains. And you have to meet those criteria to

actually be diagnosed with Budapest criteria. So by choosing this as your, your criteria, you're aligning with the actual diagnostic criteria for the disease and putting that in the clinicians hand to make that diagnosis which is the standard of practice.

Jonathan Sham Okay, so if you meet some number of criteria within..

Joseph Strunk Yeah, you have to have 2 in yeah It's. Yes.

Jonathan Sham Then it's yes or no? That is yes, you have it or no. Okay. That I mean, yeah, we definitely need to then put that in black and white here.

Sheila Rege Dr Chen does do you remember that doesn't the data putting you on the spot a little bit the Budapest criteria in the I think it was, So I think we're in line with what the data had. Good.

Christopher Chen I might, I know that Budapest criteria were in the canvas for DECO, 2021 study for complex regional pain syndrome. I might defer to our evidence reviewers, Andrea and Erika. If you guys have specific questions about some of the other studies that were included and Josh there is kind of yeah, I think there, I don't know if it's helpful to kind of like some of the other inclusion, distribution criteria, but, there.

Sheila Rege And.

Christopher Chen Our references from the evidence vendor that can document that is helpful.

Sheila Rege Yeah, I, I think it was, and Erika, I think you're on the line of somebody can comment. I just wanna make confirmation that it was in the studies.

Erika Brodt Yeah, so Appendix. Hi, this is Erika Brodt. So Appendix G tables, let's see, G. 11 through I think it's 13.

Sheila Rege So what page is that on? I have that the 191 pages.

Erika Brodt So yeah, so it starts on page 140, hold on, I'm sorry, I'm scrolling here, 145 in the appendix. So these tables list the inclusion and exclusion criteria for all the trials. So it's organized by crossover, parallel and then NRSI so unfortunately not by diagnosis but we you know we could look through and see the diagnosis I think pretty, pretty easily the only place I'm seeing the Budapest specifically called out is in the Canós-Verdecho. But there are, I mean, yeah, we list kind of, ad nauseam the inclusion and exclusion criteria for all the all the studies there.

Sheila Rege And pulling the Budapest. Do you have to meet 3 out of 4 criteria? What did they say in the trial? You know, you how many criteria did they have to meet? Do you, do you know? In our studies. It's just a new topic. So I just wanna make sure that we're in line with the evidence that was presented.

Erika Brodt	Sure, I mean, do you want me to read what they? The inclusion criteria was for that one study.
Andrea Skelly	It just.
Sheila Rege	Yeah. Right. Okay.
Erika Brodt	What would be? Okay, yeah. So the, yeah, the Canós-Verdecho. So they said patients had to be diagnosed with CRPS with upper limb involvement according to the Budapest criteria. And with a, dolar neuropathic pain four questions, questionnaire score of greater than or equal to 4. Because it's sensitive or I think for CRPS, something like that they say. And then they had to have a lack of response defined as no significant pain reduction or improved function to conventional treatment or minimally invasive techniques. They have to be a candidate for SCS. And then they give some age restrictions. They had to have a trial period. So that's their criteria for that study.
Sheila Rege	Would anybody want to say anything about? Just Budapest criteria, do we wanna make our language more consistent with what Erika just said. Anybody wanna help us out with this? This, this is not my field, so I'm. I don't. I wanna make sure we're consistent with what was in the trial. Janna, have you used the Budapest criteria?
Janna Friedly	Yeah, and I guess I'm a visual person, so I'm trying to reconcile with just that.
Erika Brodt	Yeah.
Janna Friedly	With, with the criteria. So I'm trying to pull that up, as we.
Erika Brodt	Sure.
Janna Friedly	As we talk. Okay.
Sheila Rege	Oh good, you have the same thing where I finally found the appendices.
Erika Brodt	Yeah. And I don't know if anyone could share it on your end. I don't know if that's doable, but I understand being a visual, visual person.
Sheila Rege	The other thing, Erika, while Janna is looking at the actual study. Did, was there anything on chronic regional pain syndrome? We have like a psychologic evaluation, we have that, right? An appropriate treatment. Oh, so we were covered with that. That's what I remember too.
Erika Brodt	Let's see, I'm sorry, are you asking if, if in the inclusion criteria they talked about that specifically.

Sheila Rege	I remember them doing it. I was just pulling up that 191 pages and I, what we have it covered.
Erika Brodt	Okay. Alright. Great.
Sheila Rege	So my question is, so let's hold off on the number one. Are we okay with the rest of the proposed inclusion criteria, any discussion on that? We're going to come back to point number one. If not, let's move down Josh.
Joseph Strunk	Your second bullet point would be inaccurate for the diagnosis of CRPS. CRPS is not diagnosed as, with imaging or with changes in reflexes, sensory changes. It's diagnosed by the Budapest criteria, so requiring that voids, it competes with your bullet point above.
Sheila Rege	Well, I would assume you have to actually have a normal imaging to make sure there's nothing else.
Joseph Strunk	Yeah, cause and again, that's in the Budapest criteria as a diagnosis of exclusion. So by referencing that you nicely package that disease by the standard.
Tony Yen	So can you just take out those second bullet point and everything works?
Joseph Strunk	From a clinical standpoint, yes. If you wanted to leave a point about severity that would be the only other thing. And that study quoted 4 or greater.
Josh Morse	Janna, did you find that, the table being referenced or would you like me to show it?
Janna Friedly	I would love for you to show it. I'm looking at a few things.
Erika Brodt	Oh, sorry, four or greater, yes.
Josh Morse	Did you say yes, show it or? Okay.
Janna Friedly	Yes, please. Okay.
Josh Morse	Showing the wrong screen. Erika, this is what you're referring to from Appendix G I think. Is that right?
Erika Brodt	I don't see anything yet. I'll let you know. Yes, that's it.
Josh Morse	Oh, 2 clicks, sorry. Getting that.
Erika Brodt	That's correct.
Sheila Rege	So can we, can we copy that statement. Oh, and with four questions pain. Is that something that we can do?

Josh Morse	Well, I typed in this. Yeah, upper limit. Yeah, I can copy it or I can. Yeah.
Sheila Rege	Whatever, however you want to do it.
Josh Morse	It should work.
Janna Friedly	Yeah. And this is, you know, the, that questionnaire is not something that's widely used in clinical practice. So I think.
Sheila Rege	Oh, it's not.
Janna Friedly	I would, I would recommend just including the pain score. Just saying a pain score greater than. Okay.
Sheila Rege	Well, so the Budapest criteria is not used. Is that what you're saying? Or the
Janna Friedly	No, just like the, the questionnaire, that specific questionnaire I don't think is necessary in my opinion, I would just say, greater than or equal to. Hey, well, I, again, this is. My personal belief is that we should do greater than or equal to 5 on a VAS or NRS pain scale Okay. But that's not the same thing that was in this particular study.
Sheila Rege	But we want to be consistent with the data.
Janna Friedly	Yeah.
Sheila Rege	so I think we need to say let the clinician pick one so with a pain score greater or equal to 4 on a, I don't know, and then for example, we can name this one and VAS or how would that suffice? So make sure we are anchored in data.
Andrea Skelly	There are a couple of other studies that also look at the complex regional pain syndrome. One is Creek, then Kemler, also, and they mention, an IASP with impaired function. So meet diagnostic criteria for sympathetic dystrophy established by IASP with impaired function and symptoms beyond the area of trauma. Both of those studies, that's the criteria that they use for CRPS.
Joseph Strunk	What was the date on those trials though? Cause that may predate the establishment of the Budapest criteria.
Andrea Skelly	Yeah. I think.
Joseph Strunk	So that would mean that we should probably stick with the more current.
Andrea Skelly	Creek is 2016. So you know, Kemler is older. The most recent Kemler is 2008.
Erika Brodt	Creek is up, Josh. Yeah. And Kemler does mention that just so you know that a pain intensity of at least 5 on the VAS. Janna, you were mentioning that. The Kemler study.

Andrea Skelly	And some of the studies also do list the types of conventional medical management that they considered, for inclusion criteria.
Erika Brodt	Yeah, Creek again, the VAS.
Joseph Strunk	The IASP diagnosis criteria is just the other name for Budapest. So.
Janna Friedly	Okay, yeah. The new IASP.
Andrea Skelly	Right.
Sheila Rege	What would it, would it just, we only have now less than 30 min to do the next one. Would it be okay if you leave it up to the clinician? Something about pain intensity we can say greater than 4 or 5 on a accepted, I, I mean, tomorrow's invisible pain scale may be different if it's anything like cancer. Something like that is that something we can do is to move us past this? I don't want to be prescriptive if the pain.
Janna Friedly	Yeah, Sheila just in the in the pain, the VAS or NRS pain scale is what's commonly used.
Sheila Rege	Tool changes. Okay. Okay.
Janna Friedly	That's, that's a standard acceptable. So I don't think we need to spend time belaboring that and that's that is what we put in the other failed back, back pain one and again, I, I there's a little bit between the grey zone between 4 and 5, but we're talking about moderate to severe pain which is typically 5 or above. So, I feel strongly that we put that, you know, greater than or equal to 5. That's my belief.
Sheila Rege	Okay. Is everybody okay with that Josh? Do you have any directions with you clean that up for us?
Josh Morse	Okay. So I, you're deleting reference to the DN4. Is it contradictory to leave in Budapest criteria or take that out too? I'll ask you, Dr. Friedly.
Janna Friedly	No, that's fine. The Budapest criteria is appropriate.
Josh Morse	Okay. And then is bullet point 2. This is this coming out?
Janna Friedly	Yes.
Josh Morse	Okay, thank you.
Conor Kleweno	Can I ask if we, do we have to constrain by upper limb?
Janna Friedly	Well, the studies were upper limb.
Conor Kleweno	Not, just the one.

Washington State Health Care Authority

Sheila Rege	Erika, Andrea, can you help us with that? I thought the studies were up early this is just one, but the others.
Andrea Skelly	The, the one that specifies the Budapest criteria is upper limb but looking at Creek or looking at the Kemler it was either hand or foot. So of upper or lower limb for that particular one.
Erika Brodt	Yeah, and Creek is one extremity only, but doesn't indicate.
Andrea Skelly	Which
Erika Brodt	Which, upper, lower
Janna Friedly	So you could just say according to the Budapest criteria.
Conor Kleweno	I think that would be cleaner in my perspective, but I don't see much upper limb pathology only lower.
Josh Morse	Removing the limb reference.
Conor Kleweno	Janna, any objection to removing upper?
Josh Morse	Is that what you're thinking, limb involvement, according to Budapest criteria?
Conor Kleweno	I think that's, I think you could just say CRPS according to the Budapest criteria.
Josh Morse	Okay.
Sheila Rege	And yeah, and that's pretty clear that we're thinking and with the pain scale. So it's not right, the sentence as it reads is clear. I think it is, personally. Okay, I'm moving on down to exclusion criteria.
Josh Morse	Let me scroll.
Sheila Rege	If there's no discussion, then let's make this all on one page so we can look at it. Is everybody okay with that? If I don't hear anything in 5 seconds we can move on. Yeah, yes, and I don't wanna prolong it but I've always had an assumption that with this, there was, there was important to have kind of that multidisciplinary and, and more on CRPS. With neurologists and you know pain management specialists and stuff I think we I think we would address that, correct? I mean, we didn't say anything about we didn't we want prescriptive above the multidisciplinary that's the only thing I could see, missing and I think it was in the studies. I think we mean it, but I don't think we need to add it unless somebody who does this more than me says we need to. Not hearing nothing. Let's move on to a peripheral diabetic neuropathy.
Clint Daniels	You can remove ODI and chiropractic again like the last one.

Janna Friedly	And Yeah. And you need to come up with a definition of painful diabetic neuropathy.
Sheila Rege	Erika or Andrea, can you help us with what the studies said?
Conor Kleweno	I think same questions about reflexes and EMGs as well.
Janna Friedly	Yeah, although you have to have some, or way of diagnosing peripheral neuropathy that's objective. So, you know, in the studies I think we're variable again and how they did that or some of them weren't as well-defined or that but they the Peterson which is really the only trial wasn't clear what they the Peterson which is really the only trial wasn't clear what exactly they said they did a neurologic exam but wasn't clear but it wasn't clear that that was inclusion criteria specifically. It wasn't clear that that was inclusion criteria specifically. It was used to measure outcomes but I think you do have to have a sensory and or motor and motor component, that's objectively diagnosed through either mono filament and or EMG nerve conduction. Go ahead.
Andrea Skelly	One study. I'm sorry. One study mentions Michigan diabetic neuropathy score. Peterson talks about the American Diabetes Association guidelines. Well, that's for diabetes. That's the Peterson. You're right there, there's not a lot of specificity.
Janna Friedly	And this is where, you know, given the high prevalence of diabetes and peripheral neuropathy, I think having specific criteria and guardrails, is gonna be incredibly important here.
Tony Yen	Janna, did you say that diabetic neuropathy really needs to be diagnosed with the combination of sensory and motor findings?
Janna Friedly	Well, I think it depends on what you consider to be severe peripheral neuropathy. So just diabetic neuropathy is a sense is sensory, only, but.
Tony Yen	Yeah. Yeah.
Janna Friedly	So at minimum monofilament testing, but, you could require nerve conduction study to confirm the diagnosis of peripheral neuropathy. But.
Tony Yen	For instance, Janna, I don't, I don't see nerve conduction studies commonly being done to diagnose diabetic neuropathy and really just the monofilament examination.
Janna Friedly	Yeah, I agree. I just, I have a little bit of concern that without a rigorous diagnosis that, that this is going to be. Yeah.
Sheila Rege	You mean, if I have diabetes and I have pain, then I have diabetic neuropathy.
Janna Friedly	Yeah. It's

Tony Yen	Unfortunately, that's common though.
Sheila Rege	Erika, Andrea from the studies, would you have any?
Andrea Skelly	Again, it's pretty nebulous. Slagan again, talks about this Michigan diabetic neuropathy score. And Peterson has big reference to stable neurologic status measured by motor sensory and reflex function as determined by the investigator. They don't really talk about. And he has a monofilament or threshold criteria for neuropathy. I'm not seeing anything else. Erika, are you?
Erika Brodt	No, I'm, I'm just reviewing, but I think you covered, you covered it, Andrea.
Sheila Rege	Did they have any of the studies have anything on duration of pain for diabetic because what is it 34 million people live with diabetes.
Andrea Skelly	Slagan says greater than 12 months, so the mean intensity day or night. Of, 5 or greater on numerical rating scale. And.
Erika Brodt	Yeah, Peterson is 12 months also. So, looks like minimum of 12 months. Is what they're saying 12 or greater months.
Sheila Rege	And so what do we have here? I mean, I guess we say, 12 months of conservative medical management. So that means they have to have had pain for more than 12 months. So anybody else willing to help me move this forward?
Janna Friedly	So I would, I would say must have a diagnosis of diabetes for 12 months or greater with moderate to severe again, paying greater than or equal to 5 that's neuropathic with documented peripheral neuropathy with sensory, sensory loss ad documented monofilament exam I would include in there. There's no abnormal MRI. When, when you look at the Peterson criteria they also excluded. I mean, we can go into that, but that it also excluded peripheral vascular disease and other, some other things that we should. And diabetes with a hemoglobin a1c greater than 10 and other there were other criteria that they included in that study that we might want to think about.
Joseph Strunk	Yeah, the, a1c greater than 10 was excluded. And the you also can do vibration testing which is more large fiber. Pin perk is more small fiber. You do get some there is a very small like 5% of the population that doesn't have EMG changes. But.
Sheila Rege	Yeah, we, need to stick with what the studies did and something that is, was kind of in the study, so.
Josh Morse	You just let me know if I didn't capture everything here, but you've got diagnosis of diabetes greater than 12 months on the top line here and the second bullet addresses the pain question but not the diagnosis. I don't know if you want to move this into the 1st line.

Janna Friedly	Yeah, I would say segmental sensory loss that's determined by monofilament exam and or, and, and, in nerve conduction.
Josh Morse	Like that.
Janna Friedly	Yeah, that's consistent or, you know, consistent with in a pattern, I guess it's, you know, sort of in, in a pattern consistent with. Diabetic neuropathy. Which is
Sheila Rege	Alright, I talked to one of my colleagues and he said there was something about having at least 2 evaluations not just one and I Anybody want to help me out of? Because it's such a there's no, it's subjective. It's not a lot of. Imaging documentation. Is that something that's used in clinical practice? I, he was talking about, I assume it was the monofilament, for your, sanction, vibration, all that. It's, and I don't remember that from the study, so.
Janna Friedly	No, I think there's clinically there's just. You know, some fair it's. It's a little variability, in terms of how well people do that and how. How it's determined. So It's not a great. measure. But
Sheila Rege	Okay, so any one of those comes up positive, we are saying that's diabetic neuropathy for this committing.
Janna Friedly	And I think it has to also be at the exclusion of other, or you know, that there's not another explanation for it, I guess.
Joseph Strunk	Segmental would probably be the would not be quite the accurate term that this is going to be more of like a distal.
Janna Friedly	Yeah.
Joseph Strunk	Peripheral sensory loss.
Janna Friedly	Yeah, I would just say sensory loss. Yeah.
Josh Morse	What is NCV?
Janna Friedly	Nerve conduction. Well, it should be nerve conduction study. So. It's really a nerve, nerve conduction study. Slash, Okay. Yeah, that's probably clear enough.
Sheila Rege	And we've decided. Okay.
Josh Morse	And then conservative medical, this 12 months, conservative medical management, does the PT, the CBT, do these apply? Or is this more a drug regimen as noted in the study criteria? Or is it both?

Jonathan Sham	Yeah, the second study noted gabapentin. And, so we should, I would recommend adding medication specific.
Sheila Rege	But medical therapy.
Jonathan Sham	Yeah.
Joseph Strunk	One thing that maybe just point is would it be better to just say failure of the primary medical therapy? Or cause it what if gabapentin and lyrica change as our primary agents, what if we start using something else? Our like I think it would be. Cause that's what they're saying. They said they did the 1st line, the main treatment course. So.
Jonathan Sham	Yeah, I can be glad I was navigating for naming specific drugs. It's just. I get I think just calling out the drug to be used. We use the words like medical and conservative differently in surgeries. I don't wanna get bogged down in that, but just medical management, I suppose is what you'd say here. For, a trial of drugs, drug therapy for PDN, something like that or medication therapy.
Joseph Strunk	I think if you use the EG that would be as an example of not restricting to those meds, but offering those is kind of what we wrote, what we saw referenced in the data and is at the time of the writing of this would have been the current kind of standard. Someone please correct me if I'm wrong about the EG.
Josh Morse	Folks agree, disagree. I think the studies.
Sheila Rege	I would just say trial of what they use, comprehensive, therapy, right? Conventional medical management including pharmacologic therapy or something. I think that's what was in the studies. Erika, I think, or Andrea was that, am I remembering it right? I'm pulling it up right now.
Josh Morse	I've got it on the screen, I think. Are you?
Sheila Rege	Okay.
Janna Friedly	You could say at least at least one trial of at least one or 2 appropriate medications for neuropathic pain, something like that. Yeah. As well.
Sheila Rege	Conor, you've had your hand up and I've been. Okay.
Conor Kleweno	Oh, that's okay. That let this thought finish. I think we're all in agreement. Try some medications, whatever you wanna state. My question was, I didn't see on there did the data support or having the trials, the physical therapy and CBT for peripheral diabetic neuropathy. I just, I don't treat PDN, so I wouldn't think to send them to PT, but. If the trials had it in their great.

Andrea Skelly	They just mentioned, medications, Lyrica, the Gabapentin. You know, so I mentioned ateleptic and other other types of things that might be used for chronic pain. But no PT.
Conor Kleweno	And anyone have any strong thoughts on including PT versus I think CBT is reasonable from a mechanistic or explanatory model of what's going on, but physical therapy. I don't know. It wouldn't, it wouldn't be my 1st intuition to treat as a modality for primary conservative treatment, but if other people have experience or they saw something on the studies that I missed.
Tony Yen	I would take out PT.
Chris Hearne	I wouldn't think that would be used.
Conor Kleweno	And so I would recommend taking out PT. Woah undo that. I would, I was just talking about PT specifically. But if other people have other thoughts on other things, and I just, my comment was only on physical therapy.
Jonathan Sham	I agree, Conor. You only have to point out about the medication bullet is I believe it was an or in the study we reviewed. So, usually just one drug that you had to try. Not two.
Sheila Rege	I just say, trial of comprehensive drug therapy and leave it, leave it to the clinician. They know, I mean, what if tomorrow there's a you know, something comes up. Pharmacologic, medical therapy or something like that, that way the intent of the discussion is reflected. I see Laurie shaking, so.
Laurie Mischley	Yeah. Yeah.
Sheila Rege	Yeah, that's good. You could say. I mean, gabapentin been around for ever and so you could put gabapentin so people know kind of what we're thinking about, not something fancy. Yeah
Tony Yen	Let me ask. Can I ask, was there actually evidence, within the evidence base something about CBT? The 2. Conor's point for PDN.
Laurie Mischley	Yeah. Okay.
Sheila Rege	Oh. Yeah. Go back.
Andrea Skelly	It's not mentioned in the inclusion exclusion criteria for neuropathy.
Tony Yen	Yeah, I can't say that I've ever seen anybody being referred to CBT for PDN, not to say that it doesn't work, but I just, I don't know, that's something that we have to say you got to try that, you know.

Laurie Mischley	Thank you. Shall we keep going? Does acupuncture was that a do we wanna recommend conservative therapy?
Josh Morse	Pick it out.
Laurie Mischley	Here.
Sheila Rege	I, that was that with any studies that. Do that? I know. I've seen that patients respond, but does there any of the studies that included that?
Janna Friedly	No, and the reality is there was really only one study of importance to the, the Peterson trial and that did not include any of these things and that's outside of the scope of what we've reviewed so we don't really have a way of knowing what's. Affected for. For this so we're, we're limited to what this one study. Had in their design. And so it's not really compliance with the multi-disciplinary approach. You know, the challenges that the click criteria were somewhat vague. Just.
Sheila Rege	Is everybody looking at this? Let's focus on the exclusion in, in addition to the proposed inclusion criteria. I'm changing that.
Josh Morse	I'm just reorganizing the words. You can tell me if you don't want it this way.
Sheila Rege	No, no, go ahead. I just want people to look at it once.
Janna Friedly	The other exclusion criteria, so they had the hemoglobin A1C of greater than 10, they had a BMI at greater than 45.
Sheila Rege	Okay.
Janna Friedly	As well. I don't know.
Sheila Rege	Was it less than 10 or greater than 10?
Janna Friedly	Exclusion was greater than 10.
Sheila Rege	Correct, correct, that makes sense. And the
Josh Morse	What was the second one?
Janna Friedly	Yeah. They included a BMI of greater than 45 and daily opioid dosage greater than 120 morphine, morphine equivalent and then upper limb pain intensity of 3 or 3 or more So. Yeah.
Josh Morse	I didn't get the last one, I don't think.
Janna Friedly	Upper limb pain of 3 or more.

Jonathan Sham	Can I ask about the morphine equivalent exclusion. So I understand why in a clinical trial you include that, but is there mechanistically, a reason why SCS wouldn't work if someone's on high those opioids? This is directed at Joseph.
Joseph Strunk	Yeah, that's a great question. They have, there is some evidence that patients on high doses of opioids can have opioid-induced hyperalgesia, so I think the concern there in this particular study was to use make sure that they didn't have a bunch of patients that were enrolling that have had a concurrent chronic pain syndrome. From their high use of opioids. For like for clarity in the study design that would be my guess.
Jonathan Sham	Yeah, no, no, I guess what I mean is I understand why they do in the study, but in clinical practice, is that an exclusion that you're using? Cause obviously clinical trial and real life practice are not always identical.
Joseph Strunk	Many, societal guidelines do recommend, recommending caution with high dose opioids in this range. Yes. And.
Jonathan Sham	Right, thank you. The only thing I would add is, I don't know if the workers comp and litigation exclusion make as much sense in this situation. If we feel really comfortable or really strong about keeping it, I would just make sure it's like pertaining to the PDN or something but again I, this is all different than the FBSS, so I would just favor removing it for clarity.
Josh Morse	The bullet about workers comp remove or the bottom bullet?
Jonathan Sham	The workers comp in particular.
Josh Morse	Okay.
Janna Friedly	I mean, it does it does say related. Anyway, so either way.
Jonathan Sham	Yes. Yeah, I'm having to trouble thinking of a related workers comp I guess. Yeah. I guess my understanding also is that unlike in the studies for FBSS, workers comp and litigation were not part of the exclusion criteria in those studies as well.
Josh Morse	Makes sense.
Janna Friedly	Would, with this morphine, the opioid use, should that be applied to each of the conditions?
Sheila Rege	You mean going back? To FBSS and complex regional pain syndrome, okay, and, and, what's that?
Janna Friedly	Yeah, if that's if caution is to be used. It seems like that's, that's not just isolated to peripheral neuropathy.

Sheila Rege	I'm waiting for others to say something or not.
Jonathan Sham	Yeah, I would agree with that.
Sheila Rege	Do you wanna add that into. Josh.
Josh Morse	Yep, I'll paste that into the other 2. I have a question about, upper limp pain greater than or equal to 3. Does that conflict with moderate to severe pain? It's required to be greater than, is it greater than or equal to 5 or greater than 5?
Janna Friedly	Would be greater than or equal to 5. The upper limb pain was really that was just that one study and I think trying to exclude people that have severe peripheral neuropathy affecting the upper extremities that's that wouldn't have been affected because they were focusing on lower extremity. But so I.
Josh Morse	Okay.
Conor Kleweno	I would, I would say take it out unless, you know, cause it was just for that study, but maybe, again, I don't treat PDN.
Janna Friedly	Okay.
Conor Kleweno	I don't know, maybe Joe or somebody. Is there a lot of, a, yeah, the, the, the scene and this modality is utilized for.
Joseph Strunk	Yeah, I personally haven't seen a lot of upper extremity peripheral. That's my experience.
Conor Kleweno	Good. Were we okay taking out the upper limb pain greater than 3? Is that what we were saying? Janna, you're okay with that?
Janna Friedly	Yeah, that's fine.
Joseph Strunk	With, as I'm looking at this, the other thought I was just having is the requirement of a 50% reduction in chronic opioid medications. During that trial period, that's a pretty radical decrease in opioids for those patients in a very short period of time is likely to precipitate withdrawal.
Laurie Mischley	How would you be proposed rephrasing that or just delete it or what do you what would be your suggestion?
Joseph Strunk	I think that the intent is a reduction in medications, not necessarily, and if opioids are part of that, that's great, but If you can demonstrate a reduction in the need for additional medications or a functional improvement that those two kind of create opportunity to demonstrate effect beyond just a numerical pain score. But also it would be more pharmacologically feasible for a patient that's on opioids.

Laurie Mischley	So change, oh, remove the 50% and just say reduction in pain medications.
Joseph Strunk	Yeah, chronic pain medications. Or yeah, pain medications.
Janna Friedly	Where did that? Where did that? This I think was, suggested by. Dr.Chen, maybe we can ask him. If there was a specific rationale for that 50% reduction. Okay.
Josh Morse	Chris, are you there?
Janna Friedly	No.
Christopher Chen	Sorry, Joshua with the question.
Josh Morse	Question is about the 50% reduction in chronic opioid medications, these criteria.
Sheila Rege	I think we're okay with that. Is that too short a period? That may cause withdrawal.
Josh Morse	And Janna, were you asking about the origin of those criteria?
Janna Friedly	Yeah, I was just curious where the 50%, came from. I, you know, this isn't either or, and so it's, and it says if applicable so I think there is some you know, I think that's, I'm just, I do think maybe this is a carryover from not a 7 day trial, of a stimulator but of, a 7 day trial, of a stimulator, but of a stimulator but of another longer term treatment. So I just wanted to see if there was a specific rationale for the 50% reduction but I do think demonstrating a reduction, a, a substantial reduction in pain medications. Is a good criteria.
Christopher Chen	Yeah, I think, when the AMDG discussed they were, there was interest in looking for a more objective measure of pain reduction and given that many of the claims are that it reduces opioid medicines, doses that looking for that during the trial would be helpful or I guess I think the medications and the functional improvement together with seen as more like objective evidence of improve clinical outcomes, but I can also appreciate the, the questions around like the duration of the trial.
Sheila Rege	I think we're all saying the same thing that we do want demonstration of a decrease in chronic opioid medication, you know, slow, I mean, fast tapering is what, 20% every few days, slow tapering is 10 to 25% every week. Maybe every 2 weeks, but. I think in that 2 weeks, can we? Let's put a number in there, be it 50% too much for a slow tapering. We need at least something that shows that there has been significant reduction. Can we say 25%?
Laurie Mischley	I personally don't think we should be too prescriptive simply because there's already an or there. I think if we say significant reduction in chronic pain meds, we are, you know, like I just don't. At some point I worry that we're micromanaging what a good doctor should be doing. I mean, I have to trust the surgeon is making some of these

	judgment. Hey, this person has reduced their meds, they're functionally better. Let's move on. I just would vote to not be too prescriptive.
Sheila Rege	I would agree. Yeah, the issue is that this spinal cord stimulator, if you look at our view, it's like it's over the top at 60 RVUs or something. And so there's a huge incentive. And I want to protect the patients because there's, there's a risk to it. So that's where I like it.
Laurie Mischley	But the way it's already written is an or like they don't have to reduce any pain meds as long as they have a cleaning clinically meaningful degree of improvement.
Sheila Rege	Okay.
Laurie Mischley	So we're nit picking over something that really is moot.
Sheila Rege	So do we, is everybody just significant reduction and just leave it? Oh, I'm sorry. Somebody has a hand up. Sham, Jonathan.
Jonathan Sham	No, I was gonna say the same thing that right now it's a point the way it's written but also A reduction might not be in the. Objective amount of opioids, it might be. And like the number of medications, some people might be on, you know, long interacting, something might, might be on opioids and like a gabapentin and they might be able to just stop one of the medication. Let's say that wouldn't be captured in this 50% reduction. So again, I agree of looking for a reduction but not being too prescriptive in the exact number. There's term any permutations of what this could look like to be plainly meaningful.
Sheila Rege	So significant is what you're recommending. Jonathan.
Jonathan Sham	I think the line below. Clinically meaningful. Yes.
Josh Morse	Copy that for reduction. Is that what you're suggesting?
Jonathan Sham	I think it's if you're being in guidelines, you don't really need any you don't need any modifier of reduction there. You just say reduction if you want to show something
Josh Morse	Just say reduction, okay.
Jonathan Sham	But again, the way it's written, it's a bit toothless.
Sheila Rege	Oh okay.
Josh Morse	Sheila, I just want to do a time check. I'm not rushing you. It's 10:31. You know our agenda is we have a little bit of room but I don't I don't have a sense of how close you are you think you are to having criteria for the 3 or 4 conditions at this point. So.
Sheila Rege	I think this is it. I think. This is the last one, correct?

Josh Morse	That is a decision I don't know that was made yet.
Sheila Rege	That's how Conor speak he got his hand up unless it was from a little while ago. I don't see.
Conor Kleweno	Yeah, I was just that sort of echoing what Jonathan was going over, which these, I think we should be consistent with those 2 bullets. I realize it's an or, but you know, we're being very vague about what's objective, clinically meaningful and what functional improvement means. And then we were sort of trying to be a very specific, not only in a percentage, but also in specifying opioid medications. So I just thought it may be cleanest to have those 2 bullets have some symmetry or some you know some, some consistency so it may mean that we're consistently vague reduction of chronic medications or you know, clinic objective and clinically meaningful reduction of medications and objective and clinically meaningful degree of functional improvement. Just, just some sort of consistency between the 2. Whether it's very specific or very vague. That was just my thought and, also just specifying, do we need to say opioids if we're telling them they need to. Try the gabapentin then we're saying you have to reduce your opioids. I don't again, I don't know how many of them are definitely on opioids for sure or not, but. That was just my thoughts. Keep it clean for the 2 of them.
Sheila Rege	So you don't like just reduction? Are you?
Conor Kleweno	I just, I think that it would be very easy just to make it similar between the 2. So we could say reduction of chronic opioid medications or improvement into functional outcome. That's fine. They're both somewhat vague the way it's written right now. Totally fine.
Sheila Rege	Okay. Yeah, I think.
Conor Kleweno	Thank you. I think now they're consistently vague. Or up to the discretion of the treating provider per Laurie's previous comment.
Sheila Rege	Yeah. Yeah, I agree. So.
Conor Kleweno	Because we're not providing them with the functional outcome score you know, metric they have to utilize or anything like that. So
Sheila Rege	Yeah, I think this is. In the interest of time, are you okay, Conor? I mean, if you see a big problem.
Conor Kleweno	Yes, yep, no, this is good.
Sheila Rege	Okay. So we have it all on one page. So peripheral diabetic neuropathy, any more comments on this?

Jonathan Sham	Okay, can I just confirm so that those modifiers for the trial are those present in the previous diagnose you.
Joseph Strunk	They are.
Jonathan Sham	Do we need to make similar changes then?
Josh Morse	Right, so do you wanna remove the 50% and just I think the change was. Just to reduction.
Jonathan Sham	Licenses, they would apply to all of the conditions.
Sheila Rege	Pick on people now. Chris Hearne, I haven't heard from you in a little while. Any thoughts and my suggestion we always kind of when they had it in person, we'd come up with these and then we'd take a Josh and I need a 5 min break. And then come back for voting is that or did we vote 1st and then to the final break? I can't remember.
Josh Morse	Well, 1st I think we need to go, I'll just say back to the 1st when you voted, when you last discussed this, you were breaking this out into 4 topics right when we looked I don't have the I close to the vote spreadsheet because so Val could open it as we get closer. Let me just go back to that.
Joseph Strunk	I think we broke out and started talking about non-surgical back pain and then at I think during the last meeting.
Josh Morse	Correct.
Joseph Strunk	I think Dr. Rege. There was some discussion of stepping away from that I don't recall.
Sheila Rege	It depends on, I can't remember if it was in scope. Why? I only remember 3 Josh and the non-surgical back pain. I don't know when we talk to be decided or wasn't in scope or, or had we not covered it or covered without conditions. I have to pull the minutes now.
Josh Morse	Yeah, if you want to take a break, we can look at that. I know at the 1st meeting we talked about that one. If it was ruled out, we can, we can confirm that.
Sheila Rege	Okay. So, a 5 minute break with what we need and I don't know how you can project this is if you can have 3 pages. I don't know how we can do that. Where we can see all of it. Can you make it all like in a display so
Josh Morse	Well, I, yeah, I hear what you're saying, but I think what you're where you're headed, I think is a 3 by 3 vote, right? You're gonna vote on each condition separately.
Sheila Rege	Right, but the 5 minutes was for all of us to look at the language and make sure we were comfortable.

Josh Morse	Oh, okay.
Sheila Rege	And I just don't know how to do that with I don't wanna take a break again for 5 min I want people to.
Josh Morse	I can stand here and scroll through it if you want me to. I don't know.
Sheila Rege	No, you should be, there's a display. Isn't there a display thing that you can do 3 pages in one Zoom?
Josh Morse	I don't know if it'll fit on one screen.
Sheila Rege	We're starting a break, 10:38. We'll give you 7 min, come back at 10:45. Yeah. And in the meantime, Josh is gonna try and project it so you can see all 3 use the magnifying glass. Is that okay with everybody? If anybody has an objection, don't break speak now. Are we going on break to review this?
Jonathan Sham	I don't have an objection of the break, but I'll just say that I don't think I'll be able to read. The text if it's displayed. Just.
Sheila Rege	Hi, John, you're younger than me. I haven't on my iPad and I make it bigger.
Josh Morse	I, like I said, I can. How about 2 at a time?
Sheila Rege	Can you read that, Jonathan?
Jonathan Sham	Yes, I thought you bet all 3 pages of each. 3, so 9 pages total on the screen. Is what I thought you were proposing.
Josh Morse	I think there's right now they're one page each. Unless I'm confused.
Sheila Rege	Yeah, I thought there was only 3 total pages. Jonathan. Okay, I'm going on a we've got it. You can put your cameras off by your peering at this.
Clint Daniels	Gosh, are you still on?
Sheila Rege	Is everybody back? Think we are. Any questions? Clint.
Clint Daniels	I'm looking the transcript from February and I'm not sure the straw poll we started with today was correct. Cause it looks like we actually voted no to complex regional pain syndrome as well as refractory low back pain. As I dig through the transcripts.
Val Hamann	Yeah, Clint, you are correct. The what we were looking at earlier was the coverage breakdown from November and we were not actually looking at the coverage breakdown for 2/16. So I can show that.

Sheila Rege	So. Clint, you said looking at the transcript no to complex regional pain syndrome and what else?
Clint Daniels	And the refractory back pain. And then I'm not quite sure on the diabetic neuropathy. I'm still trying to tease that out in the transcript.
Josh Morse	Yeah, so this is, yeah, go ahead, Val.
Val Hamann	So. Yeah, so this is the breakdown from 2/16. And again, Clint, you're correct that there was definitely some back and forth in the transcript on the non-surgical refractory chronic back pain.
Sheila Rege	So this is February 16th.
Val Hamann	Yes, and what you were looking at earlier was from November. So this was the November vote and then straw vote and then this was the straw vote in February.
Josh Morse	My apologies.
Clint Daniels	Yeah, so the, regional seemed to have changed a lot from those 2 votes particularly.
Sheila Rege	But that means we do have to do non-surgical refractory chronic back pain. And we could have asked for a vote on complex regional pain syndrome.
Conor Kleweno	Yeah, can I make, can I make a motion for that, Sheila?
Sheila Rege	Oh what?
Conor Kleweno	For the sake of time, can I make a motion that the criteria that we just went over for FBSS we could utilize for non-surgical factory chronic back pain just with changing the, description of having had surgery. Just for the sake of time, I think we had a lot of similarities between those 2 conditions.
Sheila Rege	Well, let's project it. Let's, let's take our time. So let's put it up and I like that idea. And put the FBSS criteria and see if anybody has any input on that.
Conor Kleweno	Obviously we would remove the 12 months post-surgery. But looking to see if anybody else agrees if we could just utilize this for that same, for the sake of time.
Janna Friedly	I would agree with that.
Tony Yen	I agree as well.
Christoph Lee	I agree.

Sheila Rege	Any other changes asked for? If not, then we are going to move through of voting. And so this will be the starting the discussion on the final vote. Is that okay with everybody? I'm sorry, at my computer, I'm gonna go get a charge cord.
Clint Daniels	Okay. Should we, you look at the complex regional pain? Cause it looks like in February, we anonymously said or unanimously said not covered.
Sheila Rege	It was done.
Clint Daniel	Even though we just spent.
Sheila Rege	Correct. That was a straw call.
Josh Morse	Well, you're gonna vote on each one. And if you, I think it's, I hope it wasn't a waste of time to develop these criteria. People may still vote to cover this with criteria or they may vote to not cover it. These would be the criteria that you would be voting for if you voted to cover it with conditions. Does that make sense, Clint?
Conor Kleweno	Yeah.
Clint Daniels	Yes, I just wanted to point out that everybody said not covered and nobody said coverage with conditions in February. So I'll just point that out and then. Yeah, everybody votes as they vote.
Sheila Rege	I agree. I should have picked that up. So really, thank you for picking that up. Chris, I'm still gonna pick on you since you haven't had any, a lot of heartache or insights on this so anything you would like to add
Chris Hearne	I, like what we've done with the conditions. I have to confess that I don't think I was present during the February meeting, so some of this is a little bit hazier for me then it otherwise would be, but I don't have any big objections to the conditions we've outlined. I think these look pretty good.
Sheila Rege	Okay, but so and that was something that I think Josh was trying to explain was you know, since we're all over this is a 3rd meeting if you were any of them and we had encouraged people to look at all the literature again to prep us so I would really love it if all of us could participate in the vote. Unless understandably you have a conflict at which point say I have a conflict. So if everybody's okay, I think, I didn't mean to pick on you.
Josh Morse	Yeah, and let's, like, so what was the committee was provided as was everybody with all of the information provided throughout the course of these meetings that includes their presentations from the medical directors, the presentations from the public at the November meeting, the evidence report and presentations and the transcripts so everything has been available to the committee and linked for your review and consideration.

Sheila Rege	Right. So let's, let's go in order. Oh, so Chris, do you need any more? I don't want to pick on you, but I'm just wanna make sure everyone is heard. Do you need any more information? Any questions? You're good.
Chris Hearne	So, for, and I missed what, Clint, I think you were saying which one of these everybody had unanimously straw polled to not cover was that the complex regional pain or did I miss hear that?
Sheila Rege	It was the complex regional pain.
Clint Daniels	Yes, I was.
Chris Hearne	Can somebody because I think when I look back at my original straw poll I had I think I had been leaning towards cover with conditions. I wonder if somebody can just really briefly, if you can recall, discuss what the what how that conversation went to February just so I have an idea.
Conor Kleweno	Do you want to display the February poll up so we can understand what he's asking.
Josh Morse	Yeah, so this was the straw polling on where you were headed. Covered versus not covered or covered with conditions.
Janna Friedly	And I think it might be helpful to go back also to the, the other tab where you have the evidence, the safety. And, see, because I think, you know, where we started, Chris, at the last meeting was reviewing, reviewing this, and just noting that this of all topics there's discrepancy between where we're rating safety, efficacy, and, cost-effectiveness and the vote. And this one in particular, it was it was I think striking that difference and not in line and, and so we had some discussion back and forth about why we were consistently saying there was there was risk and equivocal data. But some cover with conditions. So I think that was from a high level why we had that conversation.
Sheila Rege	And I know it though. It's every meeting we've had a few other people not there. Is anybody else here that has questions before, you know, we. And it's only because we've been this is the 3rd meeting, before we proceed to the final vote given the the cover with conditions language. It's not. It's 10:56 and we are supposed to 11:05 open the line up for public comment on the bariatric so If you've got a staff, keep track of that. Let us proceed with, our determination for feel and if it's okay to fail back surgery and then what do non-surgical. Josh and Melanie and Val do it whichever way you have it organized. Go ahead. I'll let you.
Val Hamann	Josh, did you want me to do the votes. Perfect. Okay, so let's start with Conor Kleweno for failed back surgery.
Josh Morse	Yeah, please.
Conor Kleweno	Oh yeah, and are you gonna be projecting our straw vote or not?

Washington State Health Care Authority

Val Hamann	Josh, did you wanna project the, the coverage criteria with this as or you just want the straw vote?
Josh Morse	Let's if you can can you do how about I'll project them my read only copy of the what am I trying to do here? I believe I have the spreadsheet, right. So Dr. Kleweno asking for the straw vote. We're starting with failed back surgery syndrome. I think this is what you're asking to see, Conor, is that right?
Conor Kleweno	Yeah, just for me and I maybe other members just keeps us organized into our categories and what our choices are for.
Josh Morse	Yeah, so.
Conor Kleweno	So for me, in my vote for failed back surgery syndrome, is not covered.
Josh Morse	And Val's recording this on a different sheet, not the one that I'm operating here. I'm just showing this to you just FYI.
Val Hamann	Okay.
Josh Morse	We can see the other one after we complete the votes.
Conor Kleweno	Oh, oh, I see that it could be confused. You don't have a blank version of this, I see. Okay.
Val Hamann	Yeah, I have that. I have. The blank version. These are from this vote that Josh is showing is from February.
Conor Kleweno	Yep, got it. Thank you.
Val Hamann	Okay. Christoph Lee.
Christoph Lee	Cover with conditions discussed today.
Val Hamann	Laurie Mischley.
Laurie Mischley	Cover with conditions.
Val Hamann	Sheila Rege.
Sheila Rege	Not covered.
Val Hamann	Jonathan Sham.
Jonathan Sham	Cover with conditions.

Washington State Health Care Authority

Val Hamann	Tony Yen.
Tony Yen	Not covered.
Val Hamann	Chris Hearne.
Chris Hearne	Covered with conditions.
Val Hamann	Janna Friedly.
Janna Friedly	Not covered.
Val Hamann	Clint Daniels.
Clint Daniels	Covered with conditions.
Val Hamann	Okay, and then we'll go down to non-surgical refractory back pain, Clint Daniels.
Clint Daniels	Covered with conditions.
Val Hamann	Janna Friedly.
Janna Friedly	Not covered
Val Hamann	Chris Hearne.
Chris Hearne	Covered with condition.
Val Hamann	Conor Kleweno.
Conor Kleweno	Not covered.
Val Hamann	Christoph Lee.
Christoph Lee	Cover with conditions.
Val Hamann	Laurie Mischley.
Laurie Mischley	Cover with conditions.
Val Hamann	Sheila Rege
Sheila Rege	Not covered.
Val Hamann	Jonathan Sham.
Jonathan Sham	Cover with Conditions.

Val Hamann	Tony Yen.
Tony Yen	Not covered.
Val Hamann	Okay, and then. We'll go to. Diabetic neuropathy, painful diabetic neuropathy, Tony Yen.
Tony Yen	Not covered.
Val Hamann	Jonathan Sham.
Jonathan Sham	Cover with conditions.
Val Hamann	Sheila Rege.
Sheila Rege	Not covered.
Val Hamann	Laurie Mischley.
Laurie Mischley	Cover with conditions.
Val Hamann	Christoph Lee.
Christoph Lee	Cover with conditions.
Val Hamann	Conor Kleweno.
Conor Kleweno	Cover with conditions.
Val Hamann	Chris Hearne.
Chris Hearne	Cover with conditions.
Val Hamann	Janna Friedly.
Janna Friedly	Not covered.
Val Hamann	Clint Daniels.
Clint Daniels	Covered with conditions.
Val Hamann	Did we want to take another vote for CRPS as well?
Josh Morse	We need to do a final vote on CRPS.

Val Hamann	Yeah, okay, perfect. Sheila Rege.
Sheila Rege	Not covered.
Val Hamann	Jonathan Sham.
Jonathan Sham	Cover with conditions.
Val Hamann	Tony Yen.
Tony Yen	Not covered.
Val Hamann	Laurie Mischley.
Laurie Mischley	Not covered.
Val Hamann	Christoph Lee.
Christoph Lee	Cover with conditions.
Val Hamann	Conor Kleweno.
Conor Kleweno	Not covered.
Val Hamann	Chris Hearne.
Chris Hearne	Not covered.
Val Hamann	Janna Friedly.
Janna Friedly	Not covered.
Val Hamann	Clint Daniels.
Clint Daniels	Not covered.
Val Hamann	Okay, so. I can display what we have.
Josh Morse	Thanks, Val.
Val Hamann	So these are the votes, how you voted today.
Sheila Rege	So cover with conditions for failed back surgery, peripheral diabetic neuropathy and non-surgical refractory on back pain, correct?
Val Hamann	Correct.

Sheila Rege	And not covered for CRPS. Does anybody wanna? Any discussion? I think we're, we voted and Josh, I will let you if there's no discussion at this point, I'll let you take us through the next few steps, remembering in 3 min we have to monitor the lines in case somebody wants to call about bariatric.
Josh Morse	Yep.
Jonathan Sham	I suppose my only comment as a process measure, which maybe we can talk about later, is perhaps doing the, the vote upfront prior to spending time on hashing out conditions for diagnosis or conditions that we're not gonna cover at the end just to help be efficient with our time.
Sheila Rege	I agree and I think. But.
Josh Morse	Yeah, so, oh, I'm sorry. I apologize. Go ahead. Yeah, I think, Yeah, I apologize for not asking you that question at the start about CRPS. I do think it's, in this case, it's helpful that you went through the exercise, but it did cost a little bit of time. So, and we, do the straw voting to determine that, right? To figure out if criteria are needed for a given topic. Your vote did evolve. I'll say that. So. The next step in the process now that you've done the draft, the final the final voting on the draft for spinal cord stimulation is to note that this if this coverage is or is not consistent with Medicare coverage. And then, if it is or is not consistent with professional guidelines.
Sheila Rege	Will you project?
Josh Morse	Well, I believe you are now consistent with a Medicare, a very old Medicare, national coverage decision for. Spinal cord stimulation. Sorry, I don't think that's a consideration now. And you have much more current evidence than was applied in that, which would be the justification for the difference. If they are any, but there is, I don't believe there is at this point. And let me just make sure I'm looking at the right.
Sheila Rege	I, that wasn't my, I'm trying to figure out what page it was on, hang on, I lost my.
Josh Morse	Yeah, I can project this.
Sheila Rege	Yeah, it project that.
Josh Morse	And it looks like you're generally consistent with the guidelines that are documented here.
Sheila Rege	I would agree. Is there any discussion? Is everybody ready to go to the next step? So Josh will need to review now what happens with evidence overlooked.
Josh Morse	Yeah, so we will publish the decision today for the 3, the 4 conditions. There'll be a 2 week public comment period. During that public comment period you know, there'll be 2 questions asked of you at the next meeting about this based on the public comment

	was evidence overlooked in the process that should be considered. So was something missed. And the second question is, does the proposed findings and decisions document clearly convey the intended coverage determination based on review and consideration of the evidence. So is, is your intention clear in the language?
Sheila Rege	Is there any discussion?
Josh Morse	So, great. I just wanna say a great job. Fantastic. This has been a really, really hard one. And I appreciate your efforts over these 3 meetings. Yeah.
Sheila Rege	Thank you for leading us into it. Is there any discussion? Or are we comfortable moving on to bariatric. Thank you everybody for hanging in there. It was very difficult and it was. I'm glad we, put in as much time as we did for it.
Laurie Mischley	Thank you to our expert for showing up for 3 meetings.
Joseph Strunk	Thank you.
Sheila Rege	No, thank you. Alright. Dr. Strunk, I, really appreciate all the insights and the wisdom you provided. I, think we have somebody else stepping in for bariatric unless you want to expand your wings
Joseph Strunk	Good, I'm glad because I'd be no help on that. Thank you all. Take care.
Josh Morse	Okay. Thank you very much.
Sheila Rege	Okay. I appreciate it. And we have the lines open, correct? Because we are at that time for the public. Even though we haven't started the topic.
Josh Morse	Yeah, we haven't started the topic. Well, I think we've just elevated, Dr. Chen. Who is our clinical expert today for this topic. And there's Dr Zerzan-Thul. I think we can.
Judy Zerzan-Thul	Yes. I am the clinical expert for this topic. So. Not Dr. Chen although I'm sure he'd love to do another one.
Josh Morse	No, no, Judy Chen is our clinical expert, our non-voting member, I apologize.
Judy Zerzan-Thul	Oh yes.
Josh Morse	And, yeah, Dr. Z will be the agency medical director expert. Thank you. So I'll just, I think Val in the interest of people who may be here just for the public comment period, if people in who are attending wish to make a public comment, please raise your hand and we will document that. We will come back to the clinical to the comment period here shortly. I think we'll get there pretty soon. So we'll watch for hands up among attendees. We had nobody sign up in advance for public comment and that comes later on in the agenda here. So, Sheila, I think we're ready to go with this topic if you're ready.

Sheila Rege	I am, so I would like, just, Dr. Chen, are you on? Wanna welcome you. Give you a minute to introduce yourself. And, appreciate your being here. I don't see you though. I don't know, that's what I was looking for.
Josh Morse	I'm seeing I have.
Judy Chen	I can see myself, so I'm not sure how others may see, the, the image. Can you see me now?
Josh Morse	Yes.
Sheila Rege	Right, I see. I do, you know. So if you don't mind just introducing us, I'd be really appreciate your coming.
Judy Chen	Okay, okay.
Sheila Rege	And being here with us to help guide us, but. Do you mind just saying a few words about where you are, which practices?
Judy Chen	Absolutely. It's a pleasure to be here. Thank you for having me. My name is Judy Chen, Bariatric Surgeon, Associate Professor Surgery, University of Washington. I'm not sure how much more.
Sheila Rege	And thank you. We saw your resume. We really appreciate your being, being here. We can, with that, I think we are ready to move onto the agenda. Let's go ahead and start.
Josh Morse	So that'll be Dr. Zerzan-Thul for Health Care Authority.
Judy Zerzan-Thul	Okay, now, now we're on. So hello, everyone. If I could have the slides up, please. I'm happy to talk to you about metabolic and bariatric surgery. And I guess maybe I'll just keep talking. So, I think as you all know, obesity is a very complex and multi factorial problem. People living with obesity are at risk for a number of different chronic health conditions and several decades of research has produced evidence that bariatric surgery results in substantial weight loss and improvement or even at times resolution of weight related comorbidities, increased life expectancy and improved health related quality of life. Next slide please. And, this committee originally made a determination on this service in 2015, that was a covered with conditions for folks 18 years of age and older and since then, obesity as a general health problem has only gotten worse. There are new procedures. There is new evidence, including evidence on adolescence. There's new data on effectiveness. And then of course, as you all see on the news and in advertisements, there are new medications for this disease. I'd like to note these new medications are not part of this review. We are not comparing surgery to medications, but I just wanted to note that there is a spectrum of services to address obesity and we are looking at this one slice in that, in that treatment option. So next slide.

So these are the 8 procedures that are currently endorsed by the American Society of Metabolic and Bariatric Surgery. The ones that are have a star on them, adjustable gastric banding, biliopancreatic diversion and Roux-en-Y were all covered under the 2015 decision and so we'll be looking at all 8 of these today. Next. So the agency medical director concerns, for safety were medium at the time of our original review, there were some concerns about safety that I think have dropped since then. For efficacy, low concerns and for cost medium concerns. So next slide, we have a couple of utilization slides. I will note that most of these procedures are now done as an outpatient, except for Roux-en-Y. And so on the Medicaid side, in 2019 we had 190 clients get this service. There is not a breakdown by fee for service and MCO because there was a very small number in fee for service. The average paid per client was about $16,000 for managed care folks and about 35 for fee for service folks. And, again, you can see by based on the average, they're very small numbers in the fee for service. Next slide. On our UMP utilization, we have 4 years of data to show you. You can see that there is a difference and this is born out in the literature as well, but more people who get metabolic and bariatric surgery are female and so you can see the difference in numbers between male and female here. We have had a pretty stable amount of folks get this surgery in the last few years and the surgery in the last few years and the average is somewhere around $25- to $28,000 per procedure. Next slide.

Judy Zerzan

So these are our key questions for today. So 1st looking at the comparative clinical effectiveness of the procedures that we currently cover. Second, looking at the comparative effectiveness of the surgical procedures we do not currently cover. Looking at safety, looking at if there is differential effectiveness based on subgroups and then looking at cost effectiveness. So next slide. So our current state policies for PEBB, SEBB and Apple Health, we follow the 2015 decision with a slight modification the apple health pays for bariatric surgery on a case by case basis when medically necessary that is informed by these criteria and for Labor and Industries, this service is not covered because obesity doesn't meet the definition of an industrial injury. Next slide. So this I took out of the report, you may remember it. Looks like it got a little bit of off center, but, I thought this was sort of the best way to show you how, these types of surgeries are covered. So the Center for Medicare and Medicaid Services is that 1st column. You can see a variety of different, different criteria both in the top in terms of what are the approved populations and then in the middle the approved types of procedures and then if there's any other requirements. So the Medicare coverage criteria were adopted in 2013. It's very similar to our current 2015 coverage in terms of folks with a BMI equal to or greater than 35 with at least one comorbidity are covered and the types of procedures that are covered and the types of procedures that are covered and the types of procedures that are covered include Roux-en-Y, gastric bland, and sleeve gastrectomy. Commercial payers to sort of lump those ones in the middle, Aetna Cigna and Regence again, sort of follow this. Adult BMI of a greater than or equal to 40 with the change in all of them that for folks of Asian descent, that BMI, because of differences in body frame that BMI is 37.5. And then a BMI, at equal to or greater than of 35 with complications that can include obstructive sleep apnea, coronary artery disease, medically refractory hypertension, non-alcoholic steatohepatitis, which has a new name that I did not write down, diabetes, things like that. You can also see that for

these commercial populations adolescents are covered and they need to have their bone growth complete or be 13 or older and then have a BMI of 40 in those populations. And then you can also note in terms of the other requirements, most of those commercial payers require a trial of medical weight loss programs, at a multidisciplinary evaluation. I'd like to point out that you will notice that Oregon Medicaid has different criteria from this or in Medicaid recently reviewed this topic under their committee that is similar to this one and they updated their criteria based on that. So you can see that they are slightly different and Oregon does not have a comorbidity requirement. I know that box is checked but if you have a BMI of equal to or greater than 35, you can get bariatric surgery there. They cover adolescents for bariatric surgery and then they do not require a trial of medical weight loss program, but do require a multidisciplinary evaluation, which is part of this accreditation that I will talk about later on in the presentation. So next slide.

So since 2019 there are 22 practice guidelines that have come out. And overall, these clinical practice guidelines recognize bariatric surgery as an effective intervention for weight loss and for resolution of obesity-related comorbidities. And so you can see the numbers in parentheses are the number that recommend covering a metabolic and bariatric surgery without a comorbidity and those numbers that are there of a BMI cut off. Practice guidelines that cover different BMIs with at least one comorbidity and then for some places, diabetes type 2 is called out with a lower BMI, a BMI of equal to or greater than 30 in 8 of the guidelines and that is because in many cases having this surgery can either greatly improve your diabetes control or even have resolution of your diabetes. And then 3 guidelines talk about adolescence and either recommend coverage at equal to or greater than 40 BMI or greater than or equal to 35 with one comorbidity. Next.

So I'm gonna quickly go over sort of my summary of the evidence. And so starting with the evidence for the procedures that are currently covered. For a BMI looking at a slightly lower BMI than what we currently cover of 30 to 35, there are 2 randomized control trials. Both of them are for adjustable gastric banding and there is low certainty of evidence that it causes this procedure, decreases your metabolic syndrome, decreases high cholesterol and improves, it's a typo, it improves health related quality of life. Looking at a lower BMI of 25 to 30 for people with type 2 diabetes, there's 1 randomized controlled trial that is new since the last time we reviewed this of adjustable gastric banding. In this trial people with a procedure lost more weight but there was no differences in long term sustained remission of diabetes, no difference in changes to blood pressure, lipids, or health related quality of life. Next slide.

So next looking at a quick summary of the procedures that are not currently covered by our, our current coverage decision. There are, there are 8 trials looking at endoscopic sleeve gastrectomy, one anastomosis gastric bypass surgery, a single anastomosis duodenal ileostomy with sleeve gastrectomy, that is the SADI one I'd much prefer SADI to the long mouthful, and then intra-gastric balloon. There is not a randomized controlled trial of SADI-S, but there is of these other ones. So there are 3 trials that look at one anastomosis gastric bypass versus other covered metabolic and bariatric

surgeries and there are no differences between the procedures. So, weight loss, the rates of remission of chronic disease and improvement of quality of life all happen no matter whether you get the 3 older procedures that we currently cover or the one anastomosis gastric bypass.

There are 3 trials each. One that looks at endoscopic sleeve gastrectomy, one that looks at one anastomosis gastric bypass and one that looks at drink balloons with lifestyle and in general surgery is better. There are 2 intricate gastric balloon studies compared with sham surgery. The outcomes look at 6 months and one year and they found weight loss but their other changes in looking at changes in chronic disease or metabolic differences, we're not clinically meaningful. I should note that, intragastric balloon, and it's a typo in that one too, is a relatively newer procedure and it is a reversible procedure. So you put the balloons into someone's stomach and they stay there usually for somewhere around a time period of 3 to 6 months and then they're removed. And so I do think that that is why there are not longer term changes with intragastric balloons. So next slide. So looking at the evidence for adolescence, there are 3 small randomized controlled trials. All of them look at either Roux-en-Y or Sleeve Gastrectomy. And each of them has an average weight loss of about 20 kg once you have the procedure compared to regular medical management. There is resolution of high cholesterol and remission of type 2 diabetes in 86 to 100% of adolescents in long-term follow-up. Next slide.

Looking at safety, the Center who did our evidence review, reviewed a very large, patient data registry looking for safety concerns and in general this is a very safe procedure. The death rate is very low. You can see the percentage there and of those deaths about 58% were considered to be related to the procedure. The death rate was slightly higher for biliopancreatic diversion and for Roux-en-Y. Looking at readmissions in 30 days. That was low. 95% of those readmissions were due to symptoms that you might suspect, so nausea and vomiting, nutritional depletion or abdominal pain. Of those conditions 79% were related to the procedure and it was higher in if you had biliopancreatic diversion, Roux-en-Y or SADI. Looking at emergency department visits, that is a little higher, but still also relatively low within 30 days and again it was higher in Roux-en-Y, biliopancreatic diversion and sleeve gastrectomy. And finally, the re-operation rate in 30 days was about 1% and it was higher in the more invasive procedures. Next slide. There's been some systematic reviews now that this literature base is much larger and those systematic reviews is much larger and those systematic reviews I think also give some very good information about safety. So in these reviews looking at all cause deaths, it is 3% if you have class 3 obesity and have had surgery versus 13% with sort of usual medical care and not a surgical procedure. And so this just reflects that there are chronic diseases related to obesity and, if your body mass isn't changing, they have a higher risk of death. An interesting piece of this is the deaths related to cancer. Again, I'm sure that many of you have seen some of the studies including some that are still coming out that obesity causes increased cancer incidents and deaths related to cancer were decreased 65 to 75% if someone had had a metabolic and bariatric surgery. And looking specifically at adolescence there was 90%

on average resolution of type 2 diabetes, 77% resolution of high cholesterol, 81% resolution of hypertension and a mortality rate of less than 1%. Next slide.

So I was pretty impressed with some of those numbers, especially, thinking about cancer and so I took a deeper dive that I wanted to share with you about a study that was published in the New England Journal in 2020, called the Swedish obesity subject study. It had bariatric surgery versus usual care versus the general population in Sweden. And because Sweden keeps track of things and has a national database, they keep track of 99% of the deaths and so this is a very complete study. The numbers in parentheses next to each of those arms is the number that they looked at following this study long term and it has a median follow up of 24 years for mortality. In general, the mean life expectancy for surgery versus usual care is 3 years longer for surgery and you can see down there there's a hazard race ratio for death and for cancer death that is also lower if you've had the surgery versus usual care. These adjusted analyses, to get to the hazard ratios included all the usual criteria in terms of age, sex, level of education, but also looking at smoking status, the year of inclusion in the study, history of cardiovascular disease, glucose intolerance, diabetes, hypertension, serum cholesterol levels, serum insulin level, history of substance use. So it was very tightly, adjusted and looked at a lot of criteria for that. So I thought that this, was impressive.

So, next slide. Okay, so looking at cost effectiveness, there are 2 trials, they're very low certainty. But in general, endoscopic sleeve gastrectomy was cost effective, compared to semaglutide and lifestyle changes, and the sleeve gastrectomy was also cost-effective compared to medications. Also the intragastric balloon looking at one particular type of it or Barra was the manufacturer's name was not cost-effective. I will, say that on the face of it, even not looking at trials, it makes some sense if the surgery costs somewhere between $25- and $30,000 a year and a year of GLP1 medication costs about $20,000 a year. They end up pretty equal in cost at about a year and, so it makes sense that there are some differences in cost effectiveness. Next slide. This is just to note, we will probably review this topic again if things seem to change, there are 24 ongoing studies in metabolic and bariatric surgery including 3 in adolescence. Of those there are 11 head-to-head trials that are randomized controlled trials and 3 that are non-randomized head-to-head. And then there are 6 randomized control trials comparing surgery to lifestyle and 4 nonrandomized ones. Next slide. So, I think based on this review, I concluded the bariatric and metabolic surgery is safe and effective and it's an important part of the obesity management continuum. And so the agency medical directors are recommending cover with conditions. Yeah, we are recommending the following procedures, note the only one that we are not recommending is the intragastric balloon. We are also recommending changing the criteria to be adults with a BMI of greater than or equal to 35 and for folks of Asian to make that slightly lower. Note there is no requirement of a comorbidity for this. I'm recommending a lower BMI of 30 for adults with type 2 diabetes. We are recommending coverage for adolescents that have bone maturity and a BMI of 40 or 35 with one complication. And then, there is now in existence a metabolic and bariatric surgery accreditation, and quality improvement program. This is jointly administered by the American College of Surgeons and the American College of Surgeons Bariatric

Surgery Center Network. It includes multi, when someone gets surgery at one of these sites, it includes a disciplinary evaluation. They collect quality metrics and they follow best practices. They have, they look at their adverse events, and do quality improvement. And in Washington state there are 16, including one for adolescents. And so I am recommending that in lieu of trial of weight loss or many of the criteria require psychological evaluation that we just have people have surgery at these centers and then they get a comprehensive look. So if you wanted to look at these criteria in sort of a different way on the next slide, I, I redid this table and so you can see that last column now is our recommendations of where, where this fits and you can see that in general, we will be much closer to Oregon, who reviewed similar data that we did. And I think that's all. Any questions? Christoph.

Christoph Lee — That was great, Judy. So just to clarify the agency recommending sleeve gastrectomy, both open and endoscopic?

Judy Zerzan-Thul — Yes.

Christoph Lee — Okay. Thanks.

Judy Zerzan-Thul — Although I think it's more often done endoscopically, I think in looking at this, there's a number of you know, there's a number of choices that surgeons can make. And looking at, sort of the individual factors and so, so I didn't, the only one that I thought really was, was not very effective were the balloons. And so I wanted to allow most of them to happen and, the surgery center doing it. But Judy, your hand is up so I'm guessing as you do these procedures, you can say that in a better way than I just did.

Judy Chen — Yeah, thank you so much for, wonderful overview. I guess I wanted just to re-clarify the specific words open and endoscopic. So, laparoscopic surgery is really not done open at all. So I want to just re-clarify that term. So laparoscopic surgery. And then yes, they're separately endoscopic sleeves and just another small comment on the on the presentation laparoscopic operations, either be sleeve or Roux-en-Y gastric bypass are still done in patient. There is some outpatient, but I think the majority is still done inpatient. While endoscopic is purely outpatients. I just wanted to clarify and happy to expand more on that if needed.

Judy Zerzan-Thul — Great. Thank you. Jonathan?

Jonathan Sham — Just 2 questions. One regarding the MBSA quip accreditation. Do you have a sense of what the spectrum is of accreditation or state and where these procedures are being done currently like today? What percentage of paretic surgery being done at MBSA accredited sites.

Judy Zerzan-Thul — Judy might be able to better answer this, but my understanding is most and actually when our nurses on the Medicaid side review this, they look for that accreditation. So it's something that we, we are currently looking at.

Jonathan Sham	Okay, I just wanted to make sure there's not like a going to be an access issue if, if we're holding that accreditation is necessary while Medicare doesn't. And then the other follow question is related to will just ask, but I wanna make sure we're being very specific, cause again, I'm I don't have to, surgery, but I'm in this world, but we're talking about endoscopic or laparoscopic sleeve, because again, the data are different for each
Judy Zerzan-Thul	Yes, they are different. I included both. So yeah.
Jonathan Sham	Great. Thanks.
Judy Zerzan-Thul	Conor.
Conor Kleweno	Yeah, thanks for the great presentation there. I just had one, question for you. Just, maybe get some insight into your thoughts. We may discuss this more during the conditions slides at the end, but I see one area where divergence from most plans, but in alignment with Oregon Medicaid was the trial of medical weight loss program. And I just wanted to get your thoughts on the specifics of that and how you decided to align more, with the Oregon Medicaid versus the other ones and sort of just what went into that and thought process. I'm not saying I agree or disagree just curious.
Judy Zerzan-Thul	Yeah, that's a great question. So, first. Most folks that I think get to the, get to the surgeons office or considering this, have tried years of weight loss and have gone up and down in their weight over those years and so in sort of my thinking like why make people try and lose weight one more time. The second piece is that the evidence of the last few years is really that this surgery because it decreases weight so much makes huge differences in people's lives and really there is a big difference in chronic disease, there's a big difference in cancer, there's a big difference in death. So yes, I thought that the benefits greatly outweighed another 6 months or a year of weight loss and that if someone was ready for this surgery then they should be able to access that and that with the accreditation will sort of talk over with the patient and, and look at that but the benefits really outweighed trying to lose weight some more.
Conor Kleweno	That's great, very, very helpful. And I just didn't know it was the word medical in there. Does that, is that supposed to imply anything to us specifically? You know, there's sort of weight loss programs there's you know is there anything specific about that term that we should interpret with that or not?
Judy Zerzan-Thul	Yes, so in the past and in looking at the other commercial insurers criteria, they have a criteria that somebody has to work with a dietician. So that's the medical part of it. So, you know, it's not buying meals through Weight Watchers or, you know, doing something on your own, but having someone way you someone talk about your diet that sort of more clinical intervention.
Conor Kleweno	Thank you very much.

Sheila Rege	Yeah, other questions? That was very well done. I especially like the slide that you have up there. That's helpful in comparison. And, do we have anybody for the open public comment?
Josh Morse	Val, did anybody raise their hand for comment?
Val Hamann	I haven't seen any raised hands for the attendees.
Josh Morse	I'm sorry, can you see it again?
Val Hamann	I have not seen any raised hands for the attendees.
Josh Morse	Okay.
Sheila Rege	We, on our schedule, we have a lunch break from 11:45 to 12:15 before the evidence report. I don't know how we got back on time, but we did.
Judy Zerzan-Thul	You're right on time.
Sheila Rege	Judy, I, you work miracles you. Yeah. So, but you will be here in case questions come up after lunch? Perfect. Is everybody okay with a half hour lunch break at this point? Alright, well. Let's get energized and come back and we'll hear the evidence report. And then continue on with committee discussion. Thank you.
Josh Morse	So we'll resume at, is it 12:15? Is that?
Sheila Rege	Right, 12:15 is what the schedule shows.
Josh Morse	Excellent. I will leave the agenda on the screen. And I think we'll stop recording during lunch. Val, can you confirm that?
Val Hamann	I can definitely pause it.
Josh Morse	Okay, thank you.
Sheila Rege	Thank you.
Sheila Rege	Welcome back. Are we all here? I'm seeing most of us. If we can get to the evidence report. Oh, 1st of all, do we have questions for Judy before moving to the evidence report?
Josh Morse	For Dr. Zerzan?
Sheila Rege	Oh, sorry. Yeah.
Judy Zerzan-Thul	The excitement of 2 Judys.

Judy Chen It's rare to meet other Judy, so it's a pleasure to have one today.

Judy Zerzan-Thul Exactly. Especially in our age range. Like.

Judy Chen Yeah.

Sheila Rege All right, well, we will move to, to the evidence reports for bariatric surgery.

Shannon Robalino Hi, this is Shannon Robalino from the Center of Evidence Based Policy. Let me just pull up the slides here. And. Sorry, I haven't used Zoom in a while. I'm trying to see how to share my screen. There it is. Okay, dokey. Okay, so, this is the evidence report that we conducted at the Center for Evidence Based Policy and all, its very high level. And Judy Zerzan-Thul Dr. Zerzan and has already touched on some of these things so, may not spend as much time on some of these. Just to note again, I am Shannon Robalino and I am a senior systematic reviewer at the Center. I just wanna note that those of us who worked on this report have no conflicts of interest to disclose. And that this research was funded by the Washington Health Technology Assessment Program. So just to give you a quick overview of the. Process best. Presentation, start with a very brief background and then go into those evidence findings and then some clinical practice guidelines and conclude. So there are just a lot of abbreviations in the presentation. You are probably now all familiar with these, particularly those metabolic surgeries. I'll just highlight a couple of them here. The COE, certainty of evidence is related to the GRADE system so this is how we grade the evidence. And I'll talk more about that in just a moment.

Okay. So Dr. Zerzan has talked a little bit about this. I just want to reiterate that the 4 procedures that you see in blue here are the 4 that were previously reviewed in the 2015 evidence report and the others some of them aren't that new but those in orange are the procedures that were not reviewed previously and are included in this report and as Dr. Zerzan said, there are a little bit of a little bit complex criteria into, into how we approach these key questions. So we didn't rereview everything that's already covered. I just want to make a quick note here that there is the sleeve gastrectomy and then ESG is the endoscopic sleeve gastroplasty. So these are 2 different procedures. So these are the 8 procedures that are currently approved by the ASMBS or endorsed, you should say. Yeah. Again, just to briefly reiterate what's currently covered is anyone with a BMI over 40 so class 3 obesity, regardless of a comorbidity as long as they're an adult. Those with the BMI of 35 to 40 with any obesity related comorbidity. And then those with the BMI of 30 to 35 and type 2 diabetes. So if they had something else like hypertension or obstructive sleep apnea in that group, they would not be eligible. And again, who's not covered are children and adolescents. And does with the BMI under 30.

Just another quick overview of the differences between this 2015 and 2024 report. So you can see we have the column here that says covered under 2015 criteria. So that's again, partly what we just saw. And you can see actually back in 2015 everything was reviewed previously except this under 30 this group with a BMI under 30. So in 2024 we

did review. Those that you see here at the bottom 30 to 35 regardless of whether they comorbidity or not. Those with the BMI under 30 and children in adolescence. For those, with the BMI over 40, we only reviewed, looked for the evidence for those 4 quote unquote new procedures those that weren't reviewed previously. For those with a BMI of 35 to 40, we looked at the same 4 procedures that were not reviewed previously and the procedures that were rereviewed that were reviewed previously the adjustable gastric band, biliopancreatic diversion, Roux-en-Y, and sleeve gastrectomy. We looked for studies that had individuals with no core, comorbidity in that BMI that class 2. Let me see.

So just quickly, the way that we rated our evidence for the individual studies, we assessed risk of bias. And you'll see the, these low moderate or high on each of the individual studies when I get there. So low means that we have no real concerns about the methods and the reporting and any mitigation of biases and conflicts of interest. Where is at the other end high there's really a lot of flaws that might introduce some serious bias. Next step is that GRADE certainty of evidence ratings. So we rated weight related outcomes so this could include total weight loss, excess weight loss and BMI. Cardiovascular risk factors, such as the type 2 diabetes status had health quality of life and of course safety. So all of these studies that we included were RCT, so they all started out as having a high certainty of evidence. But then, things may have changed with due to other circumstances in there. So we have moderate, low and very low. So very low again is the other end of that spectrum that we have no confidence in the estimate of effects. And this is often due to small studies size or, limited evidence in general.

So now, findings. We'll start with this group of adults not currently covered for metabolic and bariatric surgery under the current 2015 the coverage determination. So we had 2 RCTs in this category. These are both Australian RCTs of adjustable gastric bands. The O'Brien study, they had enrolled individuals with a BMI of 30 to 35, with at least one obesity related to morbidity and there were 80 participants and you can see that the mean age was around 41, a mean, BMI of 33.6 and weight around 95 kg. And they did an initial 2 year study with 8 years follow-up. This was a moderate risk of bias. Mostly due to concerns about financial disclosures and differences in attrition between these groups. I should have said at the top of that that they compared the adjustable gastric band with 8 lifestyle intervention that included orlistat. So that intervention included behavioral modification, very low calorie diet of 500 to 550 calories, pharmacotherapy with education and professional support on appropriate eating and exercise behavior. The second one is this Wentworth report and they enroll individuals with the BMI between 25 to 30 with type 2 diabetes. Again, another small study with only 51 participants. You can see that the age, mean age was a bit higher at 53 the mean BMI was 29 and wait 82. This was initially a 5 year, study with a further 5 years follow-up, and this was a low risk of bias. In terms of the comparator here, this was a multidisciplinary diabetes care comparator and individuals were advised to do at least a hundred 50 min of moderate intensity physical activity. They were advised by a dietician to follow a calorie restricted diet and had targets set for their HVA1C of less than 7% with pharmacological treatment. So this could include metformin and insulins if

other therapies are not were not effective. So in terms of the way that we rated these 2 group, these 2 studies really, since they were different comparators, is the adults with a BMI of 30 to 35 and an obesity related comorbidity, the AGBs were more effective than the lifestyle intervention that low calorie diet plus orlistat. And this range from very low to moderate in those 4 areas. I mentioned just a bit ago the weight loss, it was a different of excess of weight lost, between 79 to 87% in the adjustable gastric band group versus 22 to 41 in those in the lifestyle group. And these differences were maintained at 10 years. The AGB is also significantly lowered the risk of the metabolic syndrome at 2 years. Had greater changes in HCL and diastolic blood pressure for that AGB group as well as significantly improved health related quality of life to the AGB group. AGBs were higher the adverse events were higher in the AGB group versus the other group. So for the other trial, that enrolled individuals that were that are in the overweight categories of BMI 25 to 30. Again, the AGBs were more effective than that multidisciplinary diabetes care. The certainty of evidence here was between very low and low because this is such a small study and both of these were only single studies for these categories. So there was more weight loss in the AGB group at 2, 5, and 10 years. AGB increased the chance of a type 2 diabetes remission and at 2 years, but this wasn't maintained long term. And AGB also provided greater improvements in diabetes control.

So now on to the next set of studies. There's 8 studies in this group. These are the procedures that we're not reviewed in 2015. So 1st up, we have 3 head to head studies. So the 1st one here on the left is the RYSA study. This is conducted in Finland and compared the one anastomosis gastric banding to Roux-en-Y and participants with the BMI of at least 35 and above and these participants did not, over the study didn't require the participants to have and related to comorbidity, but all participants did have at least one. You can see the mean age is around 46 years old, mean BMI around 44 and the weight was around 127 kg. This was a 1 year study with a moderate risk of bias. The next is the OAGB versus sleeve gastrectomy. This study was conducted in India and just to note that the study had the largest proportion of males which were 40% of the study group out of all of the RCTs that we identified. So they looked at individuals with a BMI of 30 and above and you can see here that there were slightly different criteria. So those with a BMI of 30 to 32 needed to have at least 2 obesity comorbidities and those with the BMI at 32 to 35 needed to have, at least one. And I should just note here that in these and these groups of individuals with Asian descent, 27.5 kilograms per metered squared is considered obese, class, effectively class one obesity. The main age of this study was close to 40 years, BMI of 41 and weight of a hundred 9 kg. This one was also a single year duration with 4 years follow-up. And the last study was conducted in France and this compared OAGB versus Roux-en-Y. This study enrolled individuals with the BMI of 35 and above and if those, so it can include those over 40 so those between 35 and 40 BMI needed to have at least one obesity related comorbidity. Similar to the previous studies the age range is in the low 40s with the BMI 44 and a weight of a 120 kg. The duration of this study was about 2 years.

So the next group of studies in this section are studies that looked at those unreviewed interventions versus a lifestyle intervention. So 1st up we have the IB-005 study this

compared the ORBERA intragastric balloon with lifestyle or plus lifestyle versus lifestyle alone. This was a larger study with 317 participants and those participants needed to have a BMI between 30 and 40 and at least a 2 year history of obesity. You can see that the participants here were on the lower end of the age at around 32 years old and the BMI was smack in the middle there of the range that they were recruiting of 35, weight was just under a 100 kilograms. This was a trial with one year duration and a high risk of bias and I just wanna note what that lifestyle intervention consisted of. It was a low calorie diet of 1,000 to 1,500 calories per day, daily food and exercise diary, encouragement to exercise and visits with clinical staff approximately every other week throughout the trial.

The next one here in the middle is the LIFEXPE-RT RCT comparing OAGB to a diet. This study was conducted in Kazakhstan, so 100% of the participants are of Asian descent. So they were recruiting those individuals with the BMI of 30 or to 50 who had metabolic syndrome. Mean age was around 45 years with the mean BMI of 41 and weight of 113 kg and again, the duration was a single year. And last on this particular side, we have the MERIT study which is comparing the endoscopic sleeve gastroplasty with a lifestyle intervention. In, and this is another larger study with 253 individuals and this was conducted in the US. The lifestyle intervention was moderate intensity consisting of a low calorie diet plan, 150 min of aerobic exercise every week, counseling visits and assessments during the 1st year of the study. So this was a 2 year study and just to note that, participants who are randomized that lifestyle intervention, at the end of the 1st year if they hadn't achieved at least 25% excess weight loss, they were offered the, offered to have the endoscopic sleeve gastroplasty for the remainder of the study and the study followed up these votes for 8 years. So this again in, enrolled individuals with BMI 30 to 40 with no criteria related to comorbidities. The baseline age was around 41 and a BMI of around 32 with weight around 88 kg.

And last in this section of these 8 studies, we have the intragastric balloon. This is a transpyloric shuttle. So this is a newer device compared with SHAM surgery. This is the end obesity 2 study. This is the largest study enrolling individuals with a BMI of 30 to 40. Those who had a BMI of 30 to 35 needed to have at least one obesity related comorbidity. And, you can see that they're based by means here, age was 43, BMI, 36.6 and weight around a 100 kilograms. This was a single year study. The OBALON intragastric balloon compared to SHAM surgery for the SMART study, again, a large study with the BMI of 30 to 40 and all individuals needed to have type 2 diabetes. The baseline means were pretty similar to the previous study on the screen for IGB and this study had a 5 year initial duration and 5 years follow up. And just to note that some of these intragastric balloons are placed as Judy mentioned for 3 to 6 months and some can be placed up to a year and they're often placed as a initial weight loss for those with extreme obesity, so maybe a BMI above 40 depending on and is to allow the individual to lose weight to get to a safe weight before another kind of surgery is attempted.

So in terms of the way that we assessed this group of studies, start with those with a BMI of 30 and above with or without a comorbidity. So the these are the head to head studies. So the OAGB was similarly or more effective than Roux-en-Y or sleeve

gastrectomy. And this was a, across those 4 categories. There was moderate to high certainty of the evidence in these 3 RCTs. So, total weight loss range from about 25 to 37% across all of these surgeries. Significant excess weight loss reductions favored the OAGB into the 3 studies which accounted for 80% of the participants overall. Excess weight loss range from 60 to 66 across these 3 interventions. And significant excess weight loss was maintained at 4 and 5 years for OAGB versus sleeve gastrectomy. And remission of comorbidities was really similar across all of these surgeries as well. There was a significant remission, sorry, remission of type 2 diabetes was more significant in the OAGB group versus the sleeve gastrectomy group after 5 years. And health related quality of life improved for OAGB and the Roux-en-Y and not as much in the, excuse me, sleep gastrectomy group. There were similar rates of adverse events across all of these surgeries and though there were more serious adverse events in the OAGB group versus the Roux-en-Y.

Next up, are the adults with the BMI 30 to 50 with or without, an obesity related comorbidity. So these studies, again, look at OAGB, the endoscopic sleeve gastroplasty and intragastric balloon and found those to be more effective than the lifestyle interventions. Certainty of evidence here was between low to moderate and I will note that if you are looking at the slides that were posted, these, this second bullet will look a little bit different. I noticed a big error in the version that got posted so I have amended that here and will be sure to circulate that, you know, give this to the group so that they can be posted. So these 3 surgical interventions had significantly larger reductions in weight and BMI versus the lifestyle interventions and clinically significant weight loss of, sorry, clinically significant excess weight loss of 10% or more occurred in both the IGB group and the and the endoscopic sleeve gastrectomy group compared with the lifestyle group. OAGB had larger improvements in blood pressure and triglycerides as well as a remission of pre-diabetes and diabetes in these groups compared with diet alone. There were no house related quality of life outcomes reported in any of these 3 RCTs. And, address events, serious, and the total number of events were higher for the IGB group and the intragastric sleeve gastroplasty group. In fact, 20% had their IGB removed before the 6 months that were planned for them to be in place. Last step on this side are the adults with BMI of 30 to 40 with an obesity related comorbidity. So the 2 IGBs that were compared here were off the Obalon and the Transpyloric Shuttle and both of those were found to be more effective than SHAM surgery with or without the lifestyle intervention. So there are significant improvements in BMI, excess weight loss and total weight loss at 6 months for both the IGB, both of the IGBs. IGBs has all had a very small significant change for the cardiovascular risk factors. These weren't clinically meaningful though, health related quality of lives, the transpyloric shuttle had clinically meaningful improvement in the health related quality of life tool that was used. The adverse events among all participants in the IGB groups was 94 to 100% and it was experienced you know most people experienced an adverse event. And, and in SHAM surgery, some early 70 to 98%. Is serious adverse events were rare. And again, some of around 23% had their TPS, the Transpyloric shuttle device, the device, early.

So these are the 30 day morbidity and mortality results of an analysis we conducted on the metabolic and bariatric surgery, accreditation and quality improvement program registry public files. So, Dr. Zerzan has already mentioned this, that the death rate overall, this analysis included almost 1.1 million patients having a their 1st bariatric surgery and overall you can see that the death rate was less than 1%. The greatest proportion of deaths occurred in those who underwent the biliopancreatic diversion procedure. 30 day reoperations, readmissions and emergency visits in the adult population here. So again, you can see that these are fairly low for 1.1 million patients, reoperations occurred in about overall 1%. The largest proportion were again in the BPD group. The readmissions so these are 30 day remissions. Just over 3% overall with the highest rates. So highest proportion in those, who underwent BPD at nearly 6%. In terms of emergency department visits, there were about 7% overall across all of these procedures with the highest rate at nearly 11% in the OAGB group.

So now we'll look at the studies we identified for children in adolescence. So we have found 3 studies for this population they actually all had similar mean ages so they're really just adolescents in these studies. So 1st up was the AMOS study. This was conducted in Sweden and compared RYGP, or sorry, Roux-en-Y to sleeve gastrectomy with a lifestyle intervention. 92% of the participants in this study received the Roux-en-Y so they reported all of the these operations together. The lifestyle intervention consisted of a diet of 1,500 calories per day and 60 min and moderate to vigorous exercise per day, monthly check-ins with their clinical team. These, individuals had a BMI of 35 or more and as I mentioned, the mean, there's, there's adolescents of just under 16 years and the mean BMI was 42.6 and mean weight of 122 kg, a duration of this study was 2 years. The basic study compared the adjustable gastric band with lifestyle, with a lifestyle intervention and this was conducted in the Netherlands. The lifestyle intervention consisted of regular dietary advice monitoring from a certified dietician regular exercise training and behavioral therapy. This is a small study of 59 adolescents who had a BMI of 35 or more with at least one obesity related co-morbidity. So a similar age group, 15.7 years old. BMI, 44 and weight a 129 kg. This was a 1 year study. And lastly, we have, the O'Brien study which compared the adjustable gastric band with lifestyle. This was conducted in Australia and the lifestyle intervention here consisted of a reduced calorie diet so between 800 to 2,000 per day, a target of 10,000 steps per day structured exercise of at least 30 min per day and everything was monitored with food diaries, step counts in consultations with their clinical staff. This group had a slightly higher, a mean age of 16.5 years. The BMI was pretty similar of 41 and weight again pretty similar with 118 kg this lasted this study lasted for 2 years. So in terms of our certainty of evidence here, so, for adolescence aged 13 years and older adjustable gastric bands and Roux-en-Y, and sleeve gastrectomy are more effective than lifestyle interventions. In this case, a high cholesterol resolution was more likely in the surgical groups though there were no differences in triglycerides or any of these surgeries or the lifestyle intervention. Sorry for, I should repeat say that differently. No differences in triglycerides for the Roux-en-Y, sleeve gastrectomy, or lifestyle inventions. And a small difference in triglycerides for the adjustable gastric band compared to lifestyle. There are no differences in health related quality of life for either of the tools that they use, they use the OP14 and the Rand36. AEs were really adverse

events are reported pretty, poorly in these trials. So there were no eligible studies. It included children less than the age of 13.

Again, this next couple of sides are from our analysis of that public registry. So in terms of 30 day mortality overall, I'll just point out the very small numbers of surgeries reported in this registry in individuals under the age of 18. So in just over 2,000 patients, there are 2 deaths so still a, proportionately under 1% of deaths for these procedures. In terms of re operations, readmissions and emergency department visits in these adolescents you can see here that the rates are very similar to those of the adults in this case Roux-en-Y had the largest proportion of re-operations, readmissions and emergency department visits.

So cost effectiveness, just wanna note here that you're, we're only presenting 2 of the studies that appear in the report there is a 3rd one that's a cost analysis of unspecified metabolic and bariatric surgeries in children and adolescence it's likely that these were Roux-en-Y or sleeve gastrectomy. But they had does not say it had no comparator, so no details that we can really report to you here that would be of use. So we had the Finkelstein study which was a cost effective analysis of the ORBERA intragastric balloon in adults. This was compared to commercial lifestyle programs commercial food replacement programs and anti-obesity medication. Individuals here were over the age of 18 with a BMI of at least 25 and a time horizon of 4 years. So, that is the 1st study and had a high risk of bias. The second here is cost-effective analysis of sleeve gastrectomy and endoscopic sleeve gastrectomy compared with semaglutide and a lifestyle intervention. The individuals that were, used in this cost-effective analysis were aged 40 and would be followed for 30 years and they had BMIs of 33, mean 33, 37 or 44. And we'll look at how we looked at, rated, used to take evidence on these 2 studies. So just wanted to note too here that we didn't include any economic analyses for covered populations for procedures that were previously reviewed. So for example, if there was a cost-effective analysis that was only looking at individuals with type 2 diabetes or hypertension and a BMI of 35 plus for Roux-en-Y, undergoing Roux-en-Y, we wouldn't have included that analysis. So 1st up are these adults aged 40 with the BMI of 30 to 35. Endoscopic sleeve gastroplasty was cost-effective when compared with semaglutide and lifestyle interventions. For adults aged 40 with the BMI above 35 sleeve gastrectomy it was cost-effective when compared to semaglutide and lifestyle interventions. And in adults with a BMI of 25 and above intragastric balloons were not cost-effective at any, what we missed to pay threshold compared with commercially available, not surgical weight loss interventions.

So in terms of clinical practice guidelines, you've seen a version of this already from Dr. Zerzan. Just want to point out that yes, we identified 22 new clinical practice guidelines published in the last 5 years since January of 2019. And this is just kind of a rough breakdown. So they, the guidelines will have more cover more than one of these, these groups which is why this display will not add up to 22. Just wanna highlight here that several, you know, in all of these groups of with or without comorbidity, with at least one comorbidity or with type 2 diabetes got they, there were a number of clinical

practice guidelines that included recommendations are with those lower BMIs for individuals of Asian descent. And just for information, sorry, I'll pediatric population. So there were 5 clinical practice guidelines. For looked at those with or without a morbidity and a BMI over 40. And, 4 looked at the children and adolescents with the BMI 30 to 40 and at least one comorbidity. The next several sides, I'm not going to read these out, but these are the 22 different clinical practice guidelines that we identified, those that are in blue text have there are solely addressing pediatric populations as you can see on this bullet here or include them in, their guidelines. So again, I won't go through these here for information and there are of course in the report with more details in there.

So just to conclude, what we identified. This time around compared to 2015 is we identified studies with OHGB and those with 45, sorry, with the BMI of 40 and above regardless of comorbidity status. In this case, the study we identified is with OABG with an individuals metabolic syndrome. For the 35 to 40 BMI with or without a comorbidity sleeve gastrectomy 2 intragastric balloon devices and OHGB we identified for individuals regardless of their status, it called morbidity status and one's intragastric balloon device the OBALON in individuals with type 2 diabetes. For the BMI of 30 to 35 regardless of regardless of comorbidity status, the IGB device or Orbera and endoscopic sleeve gastrectomy were identified and those did not those studies did not require a comorbidity. For AGB, OAGB and the transpyloric shuttle, intragastric balloon device, the studies required individuals to have at least one comorbidity and then again, the individuals who received the Obalon on intragastric balloon in that study were required to have type 2 diabetes. And the individuals that are considered, overweight, not obese, so would be my under 30 we identified study that 2 studies Sorry, one study that looked at, adjustable gastric bands in individuals with type 2 diabetes. For children and adolescents, we identified those 3 studies that I just discussed. For adolescents over 13 with a BMI of 35 and over and the AGP, RY, Roux-en-Y and sleeve gastrectomy.

So just in conclusion, metabolic and bariatric surgery continues to be safe and effective to reduce excess weight and resolve obesity related comorbidities across a spectrum of BMIs. The evidence in pediatric populations remains limited, but, the evidence that we did identify support selected use. Serious adverse events and deaths are very rare and across these surgeries. And, metabolic and bariatric surgeries are generally cost-effective compared with non-surgical interventions. And finally, the clinical practice guidelines have expanded their eligibility criteria particularly in recognition of differences in BMI and comorbidities across races and ethnicities as well as more inclusive of pediatric populations. So that's the end of the evidence presentation. So I'm happy to take any questions that you might have. I cannot see any hands that might be raised.

Sheila Rege — I saw Laurie's.

Laurie Mischley — I just have a quick question on page 17 and 18 that Orbera study in Avalon you rated as having a high risk of bias. Can you just talk about? Why?

Shannon Robalino	Sure, if you just give me a moment. I will pull that up and let you know. I'm just trying to get back to those slides for you. Okay. Yeah, let me just pull up the report, the full report and I can give you that information. I believe this was because of, attrition. And most of the reasons for these risk of bias in moderate and low is because of either attrition I'm just trying to find it here if you just give me a moment. I don't know if Beth or Val King want to pull that up and we can get back to that.
Valerie King	Yeah, Laurie, when you said page 17, do you mean of the report? I'm not seeing.
Laurie Mischley	From your report of your presentation. And the slide 17 in.
Valerie King	Oh, on the slides then. Okay. Okay.
Shannon Robalino	Let me just pull that. Okay.
Laurie Mischley	I almost interrupted at the time so we could just touch on this at the moment. I didn't know what you preferred.
Shannon Robalino	Yeah. Oh, no worries.
Conor Kleweno	Well, I think while we're looking for that, Laurie, I think that's a great point just to have that information on the slide. I know it's you don't wanna make the slides too busy but you know we have an average age which is of okay, good information, but the high risk of bias I think all sort of peaks our attention so having the explanation is great point. Thanks for asking that, Laurie.
Shannon Robalino	Okay, so this was the Obalonv vs SHAM. Let me just, I've pulled it up here and I just wanna make sure that I'm looking at the right. Right thing here. So, the, sorry, I'm not looking at the right thing here. Apologies. Can I come back to that in a moment? And as I said, maybe Beth can pull up the correct thing. I thought I had it right here.
Beth Shaw	I can try, if I can try and share my screen, we should be able to show you the table where all this this in. So if you look in your full report it's on page 187. And you can see all the ratings. So for the IB-005, so that's the Obarra one there was no masking or blinding there was limited follow-up. In that again you mentioned the attrition, there was concern about interest disclosure as well as funding and overall that was assessed as high risk of bias. In the SMART study, which is the old one, intragastric balloon. Again, there was no blinding in that study. Again, significant concerns here about interest disclosure as well as funding. So again that was assessed as being a high risk of bias.
Shannon Robalino	Yeah, and of course I'll add that it's pretty hard blind, you know, these procedures. Though this was it compared to SHAM surgery.
Laurie Mischley	And can I just clarify big picture as a, you know, I write papers and have to get things through, you know, I can't get something published without all of the authors disclosing

their conflicts of interest. How is it that it's going through the editorial board at the journal, but you're saying it's not meaning your standards.

Beth Shaw

I would just say what we're looking for is that potential for conflicts of interest. So these maybe people who've got financial interest you know, in that particular intervention. So maybe they're working for the company that developed. You know we make this assessment based on empirical evidence from the Cochrane review that has you know demonstrated that you know if authors have significant financial or other kind of interests you know those studies tend to be at higher risk of bias so that's what we're basing this on. We have had a discussion with you know when we've done our HTA retreats about how you know how some people do that slightly separately but, but we do that as part of our risk of bias based on that Cochrane review showing that empirical evidence.

Sheila Rege

I, I had a, oh sorry, Conor, go ahead.

Conor Kleweno

Oh, just, following up on Laurie's comment, which I think is really important. You know, there is a evaluation of a risk of bias, but it's, it's always helpful to have our own interpretation of that risk. And so you know, for me, if there, if I make an invention and I get money off of it and then I compare 2 groups with the invention and no invention and you see a dramatic impact of that invention, even though I'm biased, there may still be an effect of it and so The risk of bias may be there, but it doesn't mean there is bias and you know the blinding again and surgeries can be challenging whether or not you make incisions and that kind of thing and stuff. Yeah. So I think Laurie, your question is really important and I think that having that information really available and interpreting what the people who review this literature for us you know, understand is, a great discussion point for us because there may be true bias, there may be risk of bias. And I also think that the clinical expert often can have insight here, I know within my own field, I can tell you, I know some of the authors. I know what they're contracts are I can tell you what their royalties are for different studies that they publish so sometimes I think in this setting, even relying on our clinical expert can offer some good insight into that. And then just sort of echo your question, Laurie, and I think it's a good point for us to understand.

Beth Shaw

And I would just respond absolutely what we're not saying is that that study therefore is not to be believable, but you may be more cautious about your interpretation of that and that's why we bring all this together in that grade rating, taking into account things like the potential for risk of bias as well as other information around things like in precision, in directness, etc. So it's not the only thing we take into account when we're making that overall assessment of the certainty of evidence.

Sheila Rege

Chris.

Chris Hearne

I was just wondering, did any of these studies or many of these studies look at, nutritional deficiencies in surgical intervention groups. I hear too much about that.

Sheila Rege	Awesome.
Shannon Robalino	Actually most of these did not report any nutritional deficiencies a couple of them did, but it was really sporadic. I know there was one about vitamin D. Again, there, that information is in the report, so I can pull that up and, and. Oh, I've got part of it up and give you more details about that.
Chris Hearne	If it's not something you can find right away, that's okay. It sounds like the answer is that we just didn't. We got, I'm giving too much information on.
Shannon Robalino	Yeah.
Beth Shaw	I mean, I would just say one of the, recent position statements does say that nutritional deficiencies are emerging as a long-term safety concern for the SADI-S and the OAGS procedures.
Shannon Robalino	Hmm
Beth Shaw	So I think, you know, it is reported in some of the adverse events and we can find those details as needed. But what I would say and Judy Chen you know, as the kind of clinical expert here, I would say that's why, you know, it's the importance of that wrap around care for people who undergo these services. It's not a simple case of you want to go the surgery and therefore you know, there's no further contact about your obesity and its related conditions. It remains, you know, an ongoing need for contact with those wraparound services, including nutrition.
Judy Chen	Yeah, I think that Beth said it perfectly and that's why the NBISIP with that multi-disciplinary. A portion which has already been spoken of earlier is, is, is very valuable to ensuring the patients continue this chronic care of this particular disease.
Sheila Rege	I had a question on the adolescent. Was there, is there, was there a lower age limit? Is it 10? And then is the follow up? At least is 8 or 10 years?
Shannon Robalino	Let me pull that slide those slides back up for you. Okay. I think a couple of these did have a lower age limit of 10. But the number of individuals that they actually enrolled in that age group was less than 5. So, gotcha. Excuse me. So that's why you see that these main ages are, you know, closer to 16 because the couple of studies that did have a lower age band did not really enroll. Children. Under the age of 13.

Judy Zerzan-Thul	Sheila, this is Judy Zerzan-Thul to jump in my reading of this is that there was some concern about bone growth and so it seems like a lot of, the studies wanted to make sure that, was near complete. And or was advanced. And so that's why an, an easy way to make that cut off was to just say up 13 and above. But, some people also looked at the bones, but, the growing part, was a concern for that, from what I understand. And I don't know if Dr. Chen does adolescence, but I think there's some reasons for it that, that higher age.
Sheila Rege	Thank you. Thank you, everyone. Christophe, Dr. Lee.
Christoph Lee	Yeah, so just in terms of cost-effecting notice there's a couple cost effective analysis for gastric blooms were not cost effective but in general are some of these procedures less costly? It feels like a gastric balloon placement would be much less costly than a Roux-en-Y gastric bypass. Just in general costs, like are there large differences between these procedures?
Judy Chen	I'm happy to expand on that if you need to. Sorry, this is Judy Chen.
Shannon Robalino	I don't think. Oh. Yeah, go ahead.
Judy Chen	It depends on the type of balloon, so you need the endoscopy to place the balloon and then you need a second endoscopy to remove it 6 months later. And so that can. Because of how you remove it, you have to have under general anesthesia and so that cost actually can sometimes be up to 10,000 while a surgery is 20,000. So other balloons, the Obelon. You swallow that so you don't need an endoscopy to actually place it. And then you'd need a endoscopy to remove it. So there's some slighte nuances to that. And to answer previous question, I am actually the director of adolescent bariatric surgery and I work with Seattle Children's Hospital because we specifically want to ensure that those patients do have care with Seattle children's.
Sheila Rege	Any other questions?
Jonathan Sham	Yeah, Sheila. I have my hand raised.
Sheila Rege	Oh, I don't see it, sorry. Go ahead.
Jonathan Sham	I have a question for, Dr. Chen in the context of the evidence report particularly as it pertains to adjustable gastric banding. The data that we looked at is pretty old. I think, 2006 study and the comparators were essentially low calorie diet and orlistat What is the role of gastric banding in 2024 relative to other available gastric procedures. Do you perform it? Do people still perform it in the community? I just haven't seen that. At least when I was in training, not too, too long ago my impression it was kind of, falling out of favor, but I love your perspective on that.
Judy Chen	So what I was thinking about the slides are being presented, the slides for adjustable gastric banding is presented for patients below the BMI. 35. I think that's really the

point of those studies. It's because if you kind of think about how bariatric surgery is, there's sort of a sense of this one feels less permanent. And we like to say that the band is not really just reversible, it's actually more removable. So when you say something's reversible, it means that there's really nothing left behind, but when you have a band in place, you self-scar tissue. So what I mean by that is this particular study I, the authors are using an adjustable gastric band in these particular studies because they are really honestly looking at the BMI more not this not the device or the operation. I don't know if that clarifies, but ultimately to me this is what in the society for metabolic surgery. We want to understand do these interventions help in a lower BMI and so they're going to start off 1st with the surgery that may not be as extreme or, or, you know, viewed as kind of a little bit more irreversible like a sleeve or a bypass. So that's what these studies say to me. But to answer your question specifically, Dr. Sham is that yes, the adjustable gastric band has fallen in its popularity or the amount of adjustable gastric bands completely have really fallen in the times its place now. It's probably much less than 1% of all bariatric surgeries being performed. But it's not to say that it may not have its potential roles or that, you know, it's still an FDA approach device. I think your second question is, do I place these at the University of Washington? We don't place them, but it's not to say that they couldn't be possibly used in maybe different scenarios. They're not per se something that you know, couldn't be used in the future. I can expand if that doesn't make sense.

Jonathan Sham — Yeah, I guess I'm more just interested you alluded to it, but just understanding when you when one would choose to place and adjust gastric band versus a sleeve or bypass or switch? Given the low BMI levels you talked about and just understanding does it still have a role in our guidelines in our kind of practice policies in modern day.

Judy Chen — So I think that to answer that question because of its increase re-operation rate. I think that role it argues that it probably does not have a place in modern day, bariatric surgery. But, one could also argue that there are patients prefer not to have any other operation except in adjustable gastric band. And so I have personally placed them not at my current job, in my previous job, because patients still need a treatment option. They would like to have surgery, but they don't at all want anything resected, removed, re-anastomose. And so it is still technically something that can absolutely allow for treatment of obesity. But I think to answer that question in 2 ways. It's not really something often done because of the high reoperation rate. But or or what it is, it still does provide treatment to obesity. And in a very, very, very small group of people who may not any other operation.

Sheila Rege — Oh man. Any other questions? That was a really good explanation. Thank you, Dr. Chen. I gotta say Dr. Judy Chen now. Any other questions before we start our committee discussion? If not, I think I'm good with continuing unless somebody thinks they need a break. We usually do a break after this, I believe. But what, what others want the break is scheduled at 1 45. Does somebody want it? 5 min break and then we come back to discussion. Is that okay? What do you want the longer break? Come on, help me out guys.

Conor Kleweno	My preference is to be as efficient as possible and, finish, what we need to do.
Tony Yen	I want to push forward. Yeah. I agree.
Sheila Rege	That's what, yes. So then let's move on. Josh, if you could project committee discussion.
Josh Morse	You want to move into the decision aid? Yep, okay. We're gonna try something a little different today.
Sheila Rege	Yeah.
Josh Morse	So, Val is gonna pull up some slides.
Val Hamann	And this would be the time that if you all want to in a different browser, don't get out of the Zoom Meeting. Melanie, it looks like you have your hand up.
Sheila Rege	Oh yeah, Melanie you do.
Melanie Golob	Sorry, that was accidental.
Val Hamann	Yeah, so if you would like to jump into ttpoll.com and enter your session ID. You will be able to see the slides through there, but that is where when we are going through this decision aid slides that you'll be able to vote when we get to those slides so if you all want to jump into that. The session is going. So I know Laurie you had tried earlier and you were blocked, you shouldn't have any issues now.
Sheila Rege	If we all wanna take a minute to test that out and see if we can get in.
Val Hamann	And you should see kind of, like a clock waiting screen, while. The slides haven't been shared yet and everything like that.
Josh Morse	And
Val Hamann	So.
Sheila Rege	Does anybody have trouble with that?
Judy Chen	As the outside person here, I don't think I know what's going on. Are we supposed to click on something?
Val Hamann	Yeah. Okay.
Josh Morse	Yeah, sorry. Dr. Chen, yeah, so. We didn't do the revisit, you usually have an introduction with some background on the program in the interest of time. Because our morning went a little long, we didn't revisit. Some of the background of the program. So I'll give you a little background. I think, Val, are you gonna pull up the slides or am I gonna?

Val Hamann	Yes, I will.
Josh Morse	Okay, so Val is doing something in the background. So the committee is composed of 11 members and then one non-voting clinical expert. You are a full-fledged member without the voting privileges today. So, the committee goes through a decision process. It's based on a document we call a decision aid. Today we are actuall because we've been in a virtual environment now since the pandemic began and we're still working out some of the methodology for how we conduct these virtual meetings even though it's been a couple of years now. We're beginning to integrate some new technology today is the day where the committee Instead of doing a voice vote, we're gonna try to use an electronic voting tool. So the committee is logging in and this is new to everybody here today. Logging into a separate window to do the voting. It's all fully transparent on the back end, meaning it's being recorded. It's not anonymous. Meets all the requirements over open public meetings act. We think it will be better for the zoom environment to have, this electronic tool for the polling because we go through a series of votes the committee is about to embark on getting a sense of how everybody feels about the evidence for these procedures for different conditions, maybe different age groups. etc, etc. And then finally the committee will vote towards the end of the process on a coverage decision after potentially crafting some recommendations about what those criteria for coverage should be. Hopefully that addresses some of the questions. I know you use the chat earlier and very the very start of the meeting we said we don't use the chat in these Zoom meetings that leads to complications, I apologize for you not getting that information before we started this session. So, and I can answer any other questions or attempt to anyway that you might have about this.
Judy Chen	Thanks for the clarification.
Val Hamann	So it looks like we have 9 members in there, so we should be ready to go. So Josh, just let me know when you would like me to go to the next slide.
Josh Morse	Yeah, please. Go ahead and Sheila. I'll, We'll just quickly go through this. So, most of you saw the process overview this morning, I think it's effective to add it back in here. These are the 5 basic components of the meeting. We had a program evaluation done of this program in 2015. Also done by the Center for evidence space policy. I revisited their documentation because it's nice and crisp on what we do, but this is the composition of the agenda today for bariatric surgery. We had the state agency presentation about their experience and their recommendations. We have a scheduled public comment period, we had nobody sign up in advance for this topic and we did not have anybody indicate that they wished to comment in the open comment section. We just heard from the evidence report, yeah, the evidence report presentation and now we're into the part about committee questions and answers. And, the next part is discussion and development of a draft determination followed by a vote. I think this is familiar to most folks here. So we can move on to the next slide.

As you know, this is about achieving better health outcomes, but paying for what works. This comes from the decision aid. So the, the word document we typically look at we've just taken this from there and we're putting it in a PowerPoint presentation so we can walk through it by PowerPoint instead of scrolling through it in a Word document. So. this is what we're really looking at. Is it a safe? Is it safe? Is it effective and does it improve health outcomes for, for the populations in the technologies we're talking about and is it cost-effective? So we'll move on to the next slide.

So again, from the decision aid, what evidence is available? What is your confidence in the evidence for the outcomes that has evidence and how, applicable or generalizable is it to the questions being asked for this population. And we can go to the next slide. Okay, your directive is to give the greatest weight to the best available evidence and considering the following, the nature and source, the characteristics of the studies, the consistency across those studies, how recent and relevant the studies are and considerations of bias, which you've had a great discussion of. You know, we're always talking about this risk of bias assessment and unique impacts on any special populations. You can see that this all, all these factors contribute to your final decision. There's a reference here to the rule from the, the law that created this process that embodies this information. So we can go to the next slide.

So here's a process overview. So, again, from the rules, is there sufficient evidence that the technology is safe and effective, cost effective if not, that would imply that you're headed in a direction of not covering something because there's not evidence of that of these factors. If there is, is it true for all indications? If so, you might suggest coverage without any conditions or you might suggest. If there, if it's not, applicable to everything, you would, might head in the direction of coverage with conditions. Now, summarizing this you know, the majority of your decisions do land in coverage with conditions. There are some number I forget the percentage, I haven't done the calculation recently that end up covered with no conditions that's a relatively rare in the experience of this committee and then there's a fair number where coverage is not allowed based on this, but this is. This framework is captured in rule, where if there's not sufficient evidence, you would, be thinking about not covering if there is evidence you're thinking about coverage or coverage with conditions. And if stop me if you have questions, please. And next slide, please.

Right. So the process overview for safety, efficacy and cost. Is there evidence of effect? We look for this is actually for this topic so I believe I have the, word copy of this on my screen. So we typically preload this document with outcomes that are from the work of the evidence reviewers and so we're looking today under safety. Are there more morbidity mortality, a non-fatal outcomes short and long term complications. We would generally look for that. I think this is generic to all topics. I don't think this is specific to ours today.

Val Hamann We do have some slides that are more specific.

Josh Morse	We'll get to the specific ones. Yeah, so, as we move into the non to the voting, the straw polling on what is your take on the evidence, this is what we'll be considering. With more specific outcomes. And next slide please. Other considerations or are there alternatives and comparisons for all for those alternatives and does the evidence confirm better health outcomes versus management without the technology as a covered service. Next slide. Here we go. Okay, so, and this is for today's, is that right, Val?
Val Hamann	Correct.
Josh Morse	So we have, and this is where we typically start in your decision aid. We don't, we haven't very often gone back through, the 2 or 3 pages that lead up to this part. This is where you begin your conversation around outcomes. So these outcomes are taken from the report and the representation on the report. You know, the committee pauses here to identify whether there are other outcomes that are important in the conversation and what outcomes here are important to you. Sheila, I'll turn it back to you if you wanna move on through here.
Sheila Rege	Other questions still on this new process? If not, let's, begin by discussion now. I am, in my mind, we should probably separate everything safety, efficacy and our health outcomes into pediatrics and adult. But is there another subcategory that we. Should be, well, adolescence will be calling it. Is there another subcategory that we need to consider? If not, I'd like to actually just go through this discussion document in terms of safety and then go to the effectiveness. What would people like to help in do you have something with it pre-filled like you sometimes do with the.
Josh Morse	This is this is these safety outcomes on the left here, staff added based on the report. Yeah, so these are the outcomes that we saw reported in the presentation.
Sheila Rege	Okay. And so now you're looking for us to let me say importance of the outcome, are we gonna use a numeric score or just low medium high?
Josh Morse	Low medium high is typically how you've discussed it. I mean, I did hear one additional outcome mentioned, which was.
Sheila Rege	Okay.
Josh Morse	Nutritional deficits, I believe.
Sheila Rege	Nutritional deficits and then bone growth were the 2 in adolescence.
Judy Zerzan-Thul	Just to clarify on that. There wasn't any evidence about bone growth. There was more, It was put in cause they didn't want to affect it. So they waited until bone growth was done. So I don't know that there is evidence in terms of safety about how it may affect bone growth.

Sheila Rege: Okay.

Josh Morse: Yeah, and I not a critique of what Dr. Zerzan-Thul just said, but I think the this tool can be very effective for the group if you say, well, bone growth to me seems like a really important safety outcome and we don't have evidence for it. So you could be, that's a highly important outcome for you but you don't have confidence in the evidence of it because it wasn't presented, right? And that would be to me that's 1 of the benefits from this is all from GRADE. So I didn't make this up. Committee previously didn't make it up. This comes from all the literature on the grade process. This is how great guidelines are developed. Ranking outcomes along the way, often limiting those outcomes of importance. Sometimes before the reports are even written. So anyway, yeah.

Sheila Rege: No, I like this, shall we? Is everybody comfortable with proceeding and just, as we get called on? We can just talk about, I do wanna add the bone growth and the nutritional if you can unless somebody objects. A bone growth concern is what we would say.

Josh Morse: Yeah, so, Val, I think if you go to the right, lower. Yeah, you go. Just tab through, which is what I've done.

Tony Yen: Hey Sheila. Sheila, if there's no evidence behind bone growth. Is it just simply for discussion without evidence?

Sheila Rege: Yeah.

Tony Yen: Is that kind of just?

Sheila Rege: Concern because there was discussion about and I remember looking at one of the papers about, there was one paper that did it that a 10 year old. And so, you know, that, that's what I was asking a follow up for 8 years. Did stunt bone growth in some way. And maybe I'm coming at it as a radiation oncologist when we radiate children, we do worry about stunting bone growth there. And so we really try and put it off and often will go with chemo and start radiation. Laurie, I saw your hand up. And if people say not, no data, we can just say no data and just leave it alone. If that's okay with you.

Tony Yen: So Sheila, where I'm coming from is perhaps, you know, just focusing on the evidence.

Sheila Rege: Correct. So would you like bone growth not to be on there at all? Since there was no data?

Laurie Mischley: Well, I think we would all agree that we wouldn't, we wouldn't offer this for somebody who had not completed bone growth. I mean the data said starting with completion of bone growth then we can talk then it's on the table. I don't think any, maybe you can take a poll, but I don't think anyone would support approving this for somebody under the age of 13 or who hadn't completed their bone growth, which is how studies pitched it.

Valerie King	Yeah. This is Valerie King from the Center. Could I clarify the evidence around this?
Sheila Rege	Please.
Valerie King	The studies just simply did not enroll individuals who were adolescents who did not have bone growth plates so that's why there's not evidence around bone growth stunting or impairment in these studies because it was an exclusion criteria.
Sheila Rege	So Tony, given that, would, would you be okay? I mean, that is a, you know, safety concern. We'll put it into our exclusion criteria.
Tony Yen	Sure, I think that's fine, but kinda, do we need to discuss it a lot? Is this should be an exclusive criteria? That's all.
Sheila Rege	Well, it's good to be an, And so we can just say exclude.
Tony Yen	Alright, I'm better with that.
Sheila Rege	Any other safety concerns besides that those 2? And if not, let's go down. Now, how do we do this? Do we?
Val Hamann	So, I will re-share this slides, these slides. So, again, you will the next slide you will be presented to vote on safety the 1st question will be for adults again lumping everything together for adults and then the second question will be for adolescence. You will be presented with 10 options. So be sure to read those carefully because you know 3 will be of low risk, so low risk, low confidence, low risk, medium, confidence, low risk high confidence and so on and then the screen that will pop up for those committees who are, committee members who are voting it will be along the bottom for you so just choose the letter that correlates to your answer once everybody has answered I can see how many responses we get. We'll open it, you'll be able to see the count for each. Any other questions for that?
Sheila Rege	No, let's go ahead and do it.
Josh Morse	Yeah, and this I'm just gonna say this is no, this is a different method of voting but the voting is the same as we did last time.
Sheila Rege	Okay. Good. Are all in your yard? Okay, okay. Oh no, you'll sit there. Oh, so this is how we vote. Whether to cover bariatric surgery or not.
Josh Morse	Yep, you're unmuted, Dr. Rege.
Sheila Reg	Oh, sorry.
Val Hamann	Currently have 5 responses. We're waiting on one more response. And there it is. So you should be seeing the responses for this for adults. Did you want to discuss these before we go on to adolescence?

Sheila Rege	I don't think so. I think we're, I mean, anybody, anybody want to, we're a little spread, but we usually are, so I don't see that out of the ordinary.
Val Hamann	Okay, great. I will go on to.
Sheila Rege	Thank you.
Val Hamann	That adolescence, that pull is open. Closing that.
Sheila Rege	This is interesting because it was me who said no confidence to safety, which I know we're gonna exclude the bone growth but that's still on my mind Tony Okay. But I think this is good. We can keep going.
Josh Morse	So similar for efficacy, we preloaded with the outcome. So, weight, I believe is weight loss, health related quality of life, improvements, or changes and then cardiovascular changes, risk changes.
Sheila Rege	So does anybody wanna add anything? I think we've got this. Is, have you missing anything here?
Jonathan Sham	Would diabetes be another important one?
Sheila Rege	I know. I don't. Did they add diabetes?
Val Hamann	I did add that. Are you able to see it in the Zoom?
Sheila Rege	Yeah. I'm seeing it in the Zoom now. Yeah. Is there anything else we need to add?
Val Hamann	Okay.
Sheila Rege	Sorry, I was a little distracted there. Okay, let's go ahead and vote. And Josh, just, you can explain again on our options. It is less, the alternative and it's not confidence in that. This is what we talked about in the strategic meeting, the last one. Okay, let's go on. Alright. One was more high confidence, the rest were more medium confidence we can keep going. Is my screen stuck or?
Val Hamann	We're just waiting on one more response.
Sheila Rege	That's my name. Yes. You know what's confusing, just the staff to know it. That has your previous answer, but it doesn't it's a lighter pink or something are you guys seeing the same thing. So when a new question comes up, it's The previous answer still there in a light pink. I'm on an iPad. I wonder if that's what it's doing. Are you guys not seeing that? Okay. Alright. So we've discussed this. Let's move on now to yeah, cost.
Val Hamann	Is there anything.

Sheila Rege	Any discussion? Any additions? Yep. Let's go on to the poll.
Val Hamann	And we just have one, for our cost-effectiveness.
Sheila Rege	Right. Does on cost effectiveness, the one that, does anybody want to talk about why? Looks like most people thought it was more. Anybody who wants to talk about why they felt it was less cost effective or you okay with everything? Okay, compared to the alternative? Yeah, if not, let's. Let's talk about what, what we're thinking about and we've already decided to split it into adolescent and adults. Age, is this the place we would define adolescence or wait till we're doing? Oh, he's saying over 13 is everybody and I don't know, I'm gonna ask the radiologist is everybody over 13 and their growth plates for the bones closed?
Christoph Lee	No, it's variable. We would have to, to determine that by radiograph.
Sheila Rege	Okay. Anybody want to add anymore?
Jonathan Sham	So these are particular populations that we're?
Sheila Rege	Special populations.
Josh Morse	Yeah, for every topic required to consider special populations especially based on age, sex, comorbidity.
Jonathan Sham	I just add Asians, since they were called out specifically, several studies.
Judy Zerzan-Thul	Yes, I was going to suggest that if any other subgroups were there, I think, folks of Asian descent or one.
Sheila Rege	And in the comorbidity have anything spelled out specifically? I'm good at voting.
Val Hamann	We actually don't have a slide for this is just a discussion slide. We don't have any vote for this.
Sheila Rege	In terms of comorbidity, I. And I don't think I saw it in the studies, but and kind of practice I would assume and you consider cancer, dementia, life expectancy, stuff like that, right? Laurie has her hand up.
Laurie Mischley	I was just going to ask about we didn't, I didn't register if we talked about pregnancy in here. Can, can anyone speak to a conversation about that? I, I wouldn't have brought it up. There would be no contraindication with getting pregnant after this procedure. Obviously you wouldn't do this procedure while someone was pregnant. What, I just like to make sure that I fully understand that discussion point.

Judy Chen	We always recommend to not get pregnant within the 1st 2 years after a bariatric surgery. It's still safe to get pregnant. So in regards to the operation itself, it doesn't prevent pregnancy, but it actually people are more likely because the fertility rate improves with weight loss. And so if our patients do have any pregnancy, we absolutely make sure that they get care, maybe see maternal fetal medicine and if needed, ensure that vitamin levels so that we can help minimize any sort of things that may come from folic acid deficiencies.
Laurie Mischley	Why the 2 years?
Judy Chen	It's basically so that that metabolic rate can really get the best efficacy. And so in regards to resetting metabolic energetics, we really want the body to have the longest it can for maximum amount of time for weight loss and efficacy and sustainability. So again, it's not because they couldn't have a safe pregnancy, we just want to really make the best of the treatments or obesity and weight sustainability.
Tony Yen	Was Sheila, I was wondering if comorbidity on here is it like any comorbidity that we need to discuss as a special population really the comorbidities that are discussed within the evidence like for example diabetes, hypertension, cardiovascular disease that sort of stuff.
Sheila Rege	I think it would be just what and I would actually love to list those. That's what I was asking for. So comorbidity should we list diabetes, they had 3, right? And there was one more. Let me go back to that side.
Judy Chen	I mean, it's like.
Sheila Rege	Judy, do you remember what it was? Oh, sorry, go ahead.
Judy Chen	There's so many in regards to like hyperlipidemia, osteoarthritis.
Tony Yen	Yeah. Yeah. Yeah.
Judy Chen	Reflux. So I could list more, but I I don't wanna go into that.
Sheila Rege	It was 3 in. The. Dr. Zerzan-Thul.
Judy Zerzan-Thul	Hyperlipidemia was most noted, but, as Dr. Chen notes, it does improve a lot of different kinds of disease including reflux, including obstructive sleep apnea, including things that they're, that we didn't talk about a lot. So.
Sheila Rege	So are you okay just saying example diabetes, hypertension, and leaving it at that?
Judy Zerzan-Thu	Yes.
Sheila Rege	Good. Are you okay with that Tony?

Tony Yen	Yes, I didn't feel like we need to detail that if we kind of have a common understanding. I think we do.
Sheila Rege	So now, I think for the discussion we can move on to the straw poll and let's do adults first. And so we should open our voting.
Val Hamann	Hold on, let me relaunch that really. Okay, should be open.
Sheila Rege	Got it. Is that unanimous.
Val Hamann	Yes.
Sheila Rege	You know it's been a long time since we have that.
Val Hamann	And we'll move on to adolescence. We currently have 5 responses.
Sheila Rege	Okay. So with that now we can, let's start with adults crafting. Oh, what's this?
Val Hamann	Sorry, sorry, that was, Josh so if you want to take back over for drafting conditions and then I will plug this in later when Josh is done.
Josh Morse	Sounds good. Thank you. And Val, thank you for figuring that out and making it work today.
Sheila Rege	Yeah, that was really good. Dr. Judy Chen, are there any? So. Are there any bariatric surgical procedures that are dangerous that we should call out or we just assume that if it's bariatric surgery is bariatric surgery. Do we need to list the ones that we used? In the studies.
Judy Chen	I guess, yeah, like clarify dangerous. We all know that the mortality rate with these surgeries are very, very, very low, incredibly low. And so I think it goes back again to having that MBSAQIP center because of the long-term and partnership with, with the center to make sure that it's done with the place that has a long history and practice of caring for the patient after surgery.
Sheila Rege	Okay, and then, I assume that when they do we're assuming robotic is also included we're just gonna leave that quiet. Correct?
Judy Chen	I guess the platform of how these surgeries are performed are individual to each surgeon.
Sheila Rege	Okay, so we don't need to do we don't need to go into that. Alright, I'm looking now for cover with conditions and we've started with BMI. 32.5 and 35?
Josh Morse	Yeah, so this starting point I'll say is from Dr. Zerzan-Thul's presentation. It's that's often where we start so I preload it with that.

Sheila Rege	Right. I'm looking at the United Healthcare coverage decision for some reason they have 40.
Judy Zerzan-Thul	They do if you remember the last table that I showed you, I think some of the later evidence really shows that this is quite effective at improving morbidity and mortality of all kinds of things, including cancers, including diabetes, including cardiovascular outcomes and so the criteria that I focused on, more matches Oregon Medicaid, which more recently looked at this evidence and did a similar review to what we're doing now. I'm not sure how recently some of the other commercial payers looked at this but I think given the impact that obesity has particularly in the Medicaid population where it's more common. I think it warrants a broader coverage.
Sheila Rege	Okay, perfect. Conor? I don't know if it was Laurie first? Okay.
Conor Kleweno	Yeah. Laurie, do you wanna go 1st or?
Laurie Mischley	No, no, no, no.
Conor Kleweno	Oh, I was gonna say, so along the lines of what was just said, maybe coming from medical director or the expert any reason to consider just making it 30? Do we need to wait till they have diabetes before we allow it? I know there may be some evidence that's tying us to some of these parameters, but just maybe not to be contrarian, but just kind of throw it out there. That's the 1st thing that came to my mind when I reviewed this.
Sheila Rege	So you'd like to change that to.
Conor Kleweno	I guess my question was, is there a strong reason unless we're tied by the overwhelming evidence to these parameters, not to, to go down to 30 but.
Judy Zerzan-Thul	Most of the studies that looked at it, used 30 as a starting point or 35, sorry. And there were some studies that had a lower BMI and some of the older procedures and there really wasn't sort of a gain there that was that was seen like is it better if you get it earlier versus later but I'll also I'm also happy to have the other Judy chat about this.
Judy Chen	In regards to 35, I, it matches the ASMBS guidelines. So I think that if you were to lower that to 30, it might. Sorry in my mind depending on what the evidence really does, we don't have as robust in that category.
Janna Friedly	That sounds like that's not consistent with clinical opinion or what's, what's done clinically.
Judy Chen	Can you clarify that question? Like it’s not consistent?
Janna Friedly	So, lowering the BMI to 30 without complications, that's not consistent with clinical practice generally aside from here.

Judy Chen	So, I mean, I guess I don't really understand your question. So right now we, we work under the NIH criteria of 1991 which is over 30 years old. Because it depends on insurance. So currently, right, so I guess I don't really understand your question.
Janna Friedly	Yes, there's, there's no place that yeah, so I guess it's not it's a moot point because it's not, not covered.
Judy Chen	Yeah, I understand your question though. Good.
Janna Friedly	No, that's okay.
Sheila Rege	Thank you answered it, Dr. Judy Chen. Laurie?
Laurie Mischley	Yeah, just in the spirit of prevention and why wait until people are really sick. I just wanted to voice my opinion that I like the idea of not requiring people to have diabetes and all these secondary problems. I just wanted to express my support of getting to people early and intervening where we can for the sake of prevention.
Sheila Rege	So you're saying just anybody with a BMI over 35.
Laurie Mischley	I believe that's the agency's suggestion is that we not require people to develop these secondary outcomes associated with, with obesity before being eligible for this surgery. And I like moving that direction. I don't think it makes sense to wait until people get sicker and sicker before we help them.
Sheila Rege	That's. And I've just been pulling other insurance and state guidelines and that's different so we would be ahead of the, the pack, if that's what we want to do. I feel for you because this is, this does have good evidence of reducing long term complications.
Josh Morse	I'm not hearing a change though, right? Dr. Mischley didn't suggest a change.
Sheila Rege	No. She did. She wants to get rid of the diabetes.
Josh Morse	Well, the diabetes lowers the requirement to get to 30. Did you say that, Laurie? Is that what you were suggesting?
Sheila Rege	So what.
Laurie Mischley	No, I'm happy with what it says right now. It's just a change from where it's been and I just wanted to say I like this direction, I think it makes sense.
Sheila Reg	Okay, so you're okay with this. You don't wanna take off?
Josh Morse	Okay.
Laurie Mischley	I'm okay with this. I'm sorry for not being more clear. Yeah, no.

Washington State Health Care Authority

Sheila Rege	Okay, I got confused. I kinda
Judy Chen	Okay, I actually interject. I'm really sorry. I apologize. I had a moment where I just looked up the ASMB guidelines. And if so, it actually does say should be considered for individuals of metabolic disease at BMI of 30. So, the priest person was correct and I want to correct it, that they were correct at 30. So this is actually not ahead of the game, In regards to the guidelines put out. Recently.
Laurie Mischley	So we should consider lowering this to 30 is your opinion?
Judy Chen	Yes, cause that is what we are. Yes, is my opinion.
Janna Friedly	But you said that that stipulates with not a metabolic condition. Does it specify what that exactly means?
Judy Chen	No, it doesn't have medical condition. So it says MBS, MBS should be considered for individuals with metabolic disease of BMI of 30 To 34.9 kg. over meters squared and then they also move forward to say 35 and over with severity of other comorbidities. So that's the current 2022 ASMBS guidelines.
Janna Friedly	Do we do we have those guidelines available for us somewhere. Is that something that can be shared with us?
Sheila Rege	Okay, Google. We could probably move on.
Josh Morse	Center had the guidelines summarized, I believe.
Sheila Rege	While they are looking for that, let's add a quick box. You wanna go for? Oh, is that me?
Janna Friedly	I know.
Shannon Robalino	Okay. Hi, I was gonna, yeah, this is Shannon, and I was going to say there is an appendices with the report that shows all of the 22 guidelines and pulls out specific pieces of recommendations around these different populations, BMIs, etc. And, there is also within the report of a small paragraph that just have that apologize, yes, tells you which well, there was a table in the presentation, but there was a little bit more detail on page 76 of the full report that has, you know, tells you that, for example regardless of comorbidity say this 9 guidelines recommend metabolic and bariatric surgery for those over 40 you know, 11 guidelines say at least one co morbidity or BMI, but there are more specific details of these guidelines
Valerie King	Yeah, so if you go to page 206 of the full report in Appendix G, that's the table of clinical practice guidelines that compares them across guideline. So starting on 206 you have the ones for adult. Sorry, that's Valerie King talking.

Janna Friedly	Yeah. Thank you. That's helpful. I'm just trying to. My audio is funny. I'm trying to reconcile the, 30 BMI with no comorbidities because all of these suggest that it's with either one comorbidity or with diabetes and it and that's where I'm just that but that's different than what I heard Judy Chen say so. I think I'm not understanding that 30 to 35 with no comorbidities where that where that is recommended.
Valerie King	So Janna, this is Valerie again. With or without comorbidities. There is not a column for 30 to 35 and I'd ask Shannon does that I think that means that we didn't find recommendations for 30 to 35 without comorbidity.
Sheila Rege	That's what you're saying there. It's 30, 34 with poorly control diabetes and for Asians it was over 27.5 but with poorly controlled diabetes.
Valerie King	With poorly controlled diabetes, yeah. And with or without comorbidities the table lists for people of Asian descent where that line is. So if you follow that down under the with or without comorbidities, the far right column, patients of Asian descent BMI. What you'll see there is that the American Association of Clinical Endocrinology, etc, that joint guideline recommends a BMI of 35 for ASMBS. And if so, that's a BMI of greater or equal to 30. So those groups have different BMI thresholds for persons of Asian descent.
Judy Zerzan-Thul	And this is, Judy Zerzan-Thul you can see the quality of those guidelines there. On looking at the procedures currently covered there were 2 RCTs that looked at the 30 to 35 BMI range with adjustable gastric banding and it was low certainty of evidence, I think because of some methodologic quality and I should pull up that one again, but, about, improved metabolic syndrome, hyperlipidemia, and health related quality of life.
Sheila Rege	What I'm seeing is that.
Tony Yen	Sheila, I'm gonna interrupt for a second because you know Chris and Christoph have been waiting for time.
Sheila Rege	I know, I mean, yeah, let's go to Christoph But before we do that, the only thing I see with this is to add that if it's Asian, if we're gonna keep 30 for diabetes we should, in this, say, Asian over 27.5, correct? But let's hold that thought. Christoph, you've been waiting a long time. And so is Chris.
Christoph Lee	Oh, I had a few points just on the language here. I agree with that. So if it's if you go back to the draft language. Adults with diabetes if adding Asian descent greater than 27.5 makes sense to me. Otherwise, yep. And then adolescence with bone maturity, I would just move the 13 plus next to adolescence, because bone maturity is not dependent on age so adolescents 13 are older with bone maturity. And then in terms of procedures, I noticed that we don't have endoscopic sleeve gastric, gastronomy, can't say that, which is different from sleeve gastrectomy. So I think we need to add endoscopic sleeve gastroplasty. And just clarify that that's Roux-en-Y gastric bypass. Not just Roux-en-Y.

Josh Morse	Can you see that part again?
Christoph Lee	Sure, remove gastric bypass. And we're all agreeing that we're not including intragastric balloons in the list of acceptable procedures. I also noticed that the 2015 language was really good and ours is pretty similar to that. They had a bullet point saying when covered patient must abide by all other agency surgery program criteria. You know, my question, I guess, is are we replacing that bullet point with this MBSA accreditation requirement. Previously, we had said when covered, patients must abide by all other agency surgery program criteria. For example, specified centers or practitioners, preoperative psychological evaluation, participating in pre and post operative multi-disciplinary care programs. But I'm find if this MBSA quip takes care of that.
Josh Morse	Judy Zerzan-Thul. Is that a question for you?
Judy Zerzan-Thul	I think it does.
Judy Chen	Yes, the MBSA CIP does include nutrition and mental health requirements.
Christoph Lee	Great, thank you.
Sheila Rege	Shann, I see you next.
Shannon Robalino	Hi, yeah, I just wanted to make a couple of clarifications there back to the guidelines and what not, where they were recommending it's for these surgeries for individuals over with a BMI of 30 to 35. They weren't restricting it to type 2 diabetes, they were saying at least one co morbidity. Right now, the coverage criteria say 30 with type 2 diabetes, but this is broadening that so that, that's, like, I will end up doing now is broadening that so that they include any kind of obesity comorbidity. I did have another, it's on there that I forgot what it was.
Sheila Rege	So you're suggesting putting, just not just diabetes, but listing other comorbidities.
Shannon Robalino	I'm just, letting you know what the this numerous guidelines are suggesting for those adults with a BMI of 30 above is to, 30 to 35 I should say is to refer them if they have any obesity comorbidity, not just type 2 diabetes.
Jonathan Sham	Okay, can I just add some clarification? I'm looking at the guidelines right now. And they actually separate out diabetes and other comorbidities. Again, this is the 2022 ASMBS bariatric surgery guidelines. And it says it's recommended for type 2 diabetes above 30, greater than equal to 30 and they say it should be considered in individuals between 30 and 35 who do not achieve substantial and durable weight loss or comorbidity improvement using non-surgical methods. So the way I read that it's saying Type 2, you don't have to try anything first get your surgery. For other comorbidities you need to try something else first. Again, that's how they're written in these, guidelines just to clarify because I know the table. It's hard to kind of decide for those nuances. And just to be

	clear, these are the ASMBS guidelines and not obviously the data that we reviewed. As we know from previous reviews, they're not always the same.
Sheila Rege	Right. Jonathan, are you looking at changing the wording?
Jonathan Sham	Shannon. Yeah, Shannon, do you mind muting? Sorry, there's some feedback on your end. What's that, Sheila?
Sheila Rege	Are you looking at changing that the wording there to include to expand it to other comorbidities.
Jonathan Sham	No, actually I'm again, I don't even have, I'm more in line with Dr. Zerzan-Thul's original recommendations for coverage again, as I said before, I just wanna make sure that we all understand what I guess that doesn't mean we have to abide by that for other technology discussions. We have, we've actually not agreed with society recommendations. We have got off the data we reviewed.
Sheila Rege	Right.
Jonathan Sham	But I just wanna make sure, cause there seem to be some confusion. I'm happy to bring it up and share screen and people wanna see it, but.
Sheila Rege	Not that.
Jonathan Sham	I'm looking at the actual recommendations and just there's a call out between diabetes and other comorbidities and they're not the same.
Sheila Rege	That's good. And then Chris.
Chris Hearne	Yeah, I definitely agree with Jonathan's point that we should be looking at the, the evidence for that 30 to 35 group rather than just relying on sort of the guidelines. I wonder if the evidence vendor can talk a little bit about what the data we have says specifically about the 30 to 35 group who do not have diabetes.
Shannon Robalino	Hi, it's Shannon Robalino again. So I just wanted also clarify that though most of the studies have a enrollment criteria of being like 30 majority of them have that. And again they had I'm just trying to count up here how many were in that range of having obesity comorbidity. There was one comparing intragastric with lifestyle and the criteria were, 2 year history of obesity. It was another with the criteria of metabolic syndrome and those who have the BMI 50 and another sorry, the last I spoke about compared the one anastomosis gastric bypass and the last here is endoscopic sleeve gastroplasty with no requirements for a comorbidity. And again intragastric balloon vs SHAM surgery enrolled individuals 30 to 40 BMI and those who had 30 to 35 have at least one obesity related to morbidity it could include anything. And there was just one study that was the Obalon intragastric balloon and it required individuals to have type 2 diabetes and you know all the cases the surgery outperformed the interventions or in the, the 2 head

to head studies they, the adjustable gastric band in 30 to 35 had to have at least one obesity related, or issue such as difficulty walking and the one with the overweight, which we're not even discussing here, that group had to have a, type 2 diabetes So I'm not sure if that helps or.

Chris Hearne — Yeah, that's very useful to know. So it sounds like the evidence, it's not it's not really splitting that 30 to 35 group without diabetes out very clearly.

Shannon Robalino — Nope, that's correct. And you know, I think I'm 1 of your, the previous slides, it was just discussion point kind of about sub-groups. There's none of these studies, really did any kind of subgroup analysis. I think one of them did one splitting. I can't remember where the cut off was, but they split it like a BMI 35 and above and 35. And below and found no differences among all the other, you know, among the outcomes.

Valerie King — Umm.

Sheila Rege — Do you wanna change or you good? Chris?

Chris Hearne — In what way?

Sheila Rege — You're okay with the way it looks now with that clarification.

Chris Hearne — Well, I do, I do wonder. You know, if the evidence did not specifically call out this, it seems like we have a group here that is not being covered, which is people without diabetes who are 30 to 35. And if I understand correctly, it sounds like. That is not specifically something we got from the evidence. So I wonder what other people think about that.

Sheila Rege — Okay, I think we have to go with the evidence, but I'm hearing what you're saying because I know other insurance plans, people working, you know, with us in the hospitals. If they have cardiovascular disease, history of stroke and they've got some blood pressure things and a fatty liver, some of the insurance companies are covering that but we didn't see it on the evidence so it's hard to go there. But.

Valerie King — Yeah, this is Valerie King. You know, I think even though there are studies that go down, to lower BMIs of 30 and in some cases even a bit lower for people of Asian descent. There's just relatively little evidence in that no comorbidity group. And I, I want to call your attention back to the information that Dr. Zerzan-Thul presented right at the beginning of this topic which is the long-term mortality benefit. And that's true, but it really comes from longer longitudinal studies where the BMI cut offs were higher. So, you know, we didn't find studies that say this, that or the other, but I think the preponderance of evidence is really about the use of these procedures people with comorbidities and in that 30 to 35 group, that's still a little bit of a gray zone. And I, there's just less evidence about that if that helps at all.

Chris Hearne — That is helpful. Thank you.

Sheila Rege	I had, a question. I know we've set the accreditation, so that's for the program or the surgeon. But looking at colleagues who have gone through this, they had to go through kind of a psychosocial behavioral evaluation and they also had to go through a complete preop, kind of a the detailed weight history and just it was in a multi discipline or just a multi-disciplinary you know kind of discussion. Is that part of this accreditation that if we say that It has to be done in a center that has the accreditation that is always followed? That's a question probably for the clinical expert.
Judy Chen	Yeah, so. In regards to each center will have those things there. As it's, I think to be clear, if it's not specifically lined in this, it might be that every patient that will get it. We have but if it's not specifically stated that should have mental health evaluation you know, well controlled mental health or dietitian, centers or not, I don't think they have to. Make sure that that patient gets it unless it's specified. But each center will have those available. So. Just to clarify that.
Sheila Rege	And this is where I'm gonna look for my committee members for help, but I've had 2 people that I know one who works for me go through this and I saw a lot of just psychosocial behavioral adjustments. So they're eating pattern changed. So they had you know, benefit for the long term. And also, really, how do you do a detail of weight history? And those are the ones that have been successful. And years ago I had somebody else do it and within a few years they were back at you know, a bad weight. So that it's not evidence-based and I don't know if there's evidence there, but it's seems like the better programs seem to incorporate that.
Judy Chen	I think, disease is hard because why it relapses or recurs can be from very many different reasons. But just to go back to specifically looking at just this draft determination, it would be good to make sure that those specific details as it was previously outlined, you know that there is mental health evaluation, you know. And I don't know all the specific things as well as nutritional education are good to make sure that that is very clear that these sites, and if they are ASMBS accredited, all those, they will do it. I think that that is important.
Sheila Rege	I don't, I don't like to be prescriptive if it's not in the studies. I'd be nice to just say encouraged or something so. I don't know.
Judy Zerzan-Thul	Yes, this is Judy Zerzan-Thul and the accredited sites do as Dr. Chen said do have the ability to do that, is that they do that if it seems like it's needed for mental health evaluation, or some for that piece. When I was reading sort of some of these things, it made me think of old criteria for transgender surgery that we used to require a lot of letters from different people including a psychologist and some of the criteria that commercial insurers have includes something like that of like a letter from a psychologist or a mental health evaluation and I felt like that was sort of too far down the path to, to require. And some folks might have some of that already. And so I wanted to leave that more to the center that has all of those, all of those people there and I think generally where they see those services are needed, they plug those people in.

Sheila Rege	Okay. I, yeah, I don't wanna make prescriptive. I just wanna say are encouraged. Because the worry is that if it's not in there, then the worries that it may not get paid. You know, I, does that make sense, Judy?
Judy Zerzan-Thul	We would pay for those things regardless even if someone doesn't get surgery. So, Yes.
Sheila Rege	Okay. And that was my more my thinking, not make it prescriptive, but saying something about it being encouraged and it's paid for, but you guys know. So I'm good with removing in. But the people that I've seen success have, they've concentrated on that. I had, I think Jonathan was before Janna.
Jonathan Sham	Thanks. Just had a question about the, should we endoscopic sleeve gastroplasty, not endoplastic under procedures. So that this is that's the one I know the least about through my training and looking at the evidence report, page 7, the intragastric balloon and endoscopic sleeve gastroplasty here kind of lumped together and both say they're more effective than lifestyle interventions. And so I just wanted to kind of make sure I understood perhaps from the data vendors the difference in data between those 2 endoscopic procedures, cause again, out of the procedure listed, that's the only endoscopic procedure that we have. So I think it's important to be differentiated. And just if. If the data are truly that different the 2 because we're not covering IGB, but we are ESG. So we will be able to review that.
Shannon Robalino	Sorry, can you, you repeat what you said on page 7 on the slide, the report. Okay.
Jonathan Sham	Nope, nope, in the final report the summary lumps them together. It says IGBT are both more effective than lifestyle interventions in adults with or without comorbidities, 3 RCTs and such, I wanna, for me, I wanna understand why we're excluding IGB, but including ESG, I'm sure there are other differences, maybe risk of bias is different, maybe it says quality evidence is the same, but I just wanted to better understand that.
Shannon Robalino	So, the intragastric balloons are effective and as I mentioned during the presentation they're often devices used for individuals that have much higher BMIs as a can Dr. Chen can speak to this better than I can of course but they're often placed to allow an individual to lose weight so that they can be have one of the other procedures and be more likely to succeed and be in a safer place to have that kind of surgery.
Judy Chen	That sounds right in regards to a staged. Do you mind muting, Shannon?
Shannon Robalino	Okay. Thank you.

Judy Chen	Thanks. So the difference between an intragastric balloon versus the endoplasty is the intragastric balloon is removed. So after 6 months that tool or intervention is gone, while an endoscopic gastroplasty does not need to be removed. So that suturing stays and creates the luminal shape of a banana. And so I think there's a slight difference to what a stage procedure a balloon is versus an endoplasty. The other aspect of, just clarification is the endoscopic Intragastric balloon, it's not only for very, very high severe, the gap in obesity treatment prior to GLPs were that people with a BMI below 35 had no good options and so endoscopic procedures were, were a little bit actually met for this group of 25 to 35 that wasn't being covered. So that's some historical content.
Jonathan Sham	Maybe I can clarify my question and maybe it's better directed to Dr. Zerzan-Thul, why in the draft recommendations is ESG Included and IGB not? Or is that something we added?
Judy Zerzan-Thul	Yeah, IGB is not covered because it is a removable device but also the data is not as good. People lose weight but the long-term data isn't there for improvement to some of the comorbidities. It may be it's 1 of the newest procedures. It may be and I actually didn't look at all of the trials that are upcoming, but the evidence evolves in this, but I think for the procedures that are on here, there is solid evidence that these work and have long term outcomes that are favorable.
Jonathan Sham	So then that's I guess why I had asked my initial question in the data review, they're lumped together and the data evidence quality and efficacy are listed is the same. So that's why I'm just trying to figure out why.
Valerie King	I'm still having, this is Valerie King, I'm still having trouble finding where that is on page 7.
Jonathan Sham	Middle of the page, under effectiveness and safety of MB in adults. It's like the 5th bullet point down.
Judy Zerzan-Thul	Is that my slides or the center slides?
Valerie King	No, this is the center's report, Judy.
Jonathan Sham	Final. Final evidence report, page 7.
Judy Zerzan-Thul	Oh, the report, yes.
Shannon Robalino	Hi, can I speak to that? So. Yeah, it's this OAGB Orbarra intragastric balloon and endoscopic sleeve gastoplasy, so these are compared to the lifestyle intervention. So that's why they're locked together there because they all compared in 3 RCTs that compared them to a lifestyle intervention and they all provided more benefit than lifestyle. So hopefully that makes it a little bit clearer.

Jonathan Sham	But yeah, so again, I'm not advocating for one or the other. I'm just trying to understand what the difference in the evidence is because we're including one and emitting the other and they seem to be lumped together here, so. I don't know if a further another table down lower in the report has that or not.
Beth Shaw	I think it's like Val said earlier and Shannon both of these procedures are effective. I don't think we have any head to head comparisons of I you know the IGB versus ESG so I think what we're just saying is that when compared with lifestyle interventions each of these are effective but we do not have that comparative data between those 2 specific procedures but correct me if I'm wrong Shannon. So yeah, if we don't have any direct evidence that says ESG is more effective than IGB and we'd exclude that but Judy your point is taken you know if these are newer procedures so there may well be other reasons why these would be not covered.
Shannon Robalino	This is Shannon again. So I intragastric balloon, as far as I'm aware of when I did background meeting on this, we're not actually very new. It's just that the approved devices have changed over time. So some of the older devices are no longer available because they dangerous or ineffective and some of them have actually just been renamed because they were sold to another company.
Jonathan Sham	And Dr. Chen, you said that the balloons are currently being used clinically for various levels of BMI?
Judy Chen	They're not, I just wanted to clarify they're not only for super high BMI stage procedure. They can also be a standalone therapy.
Jonathan Sham	Okay, so in that case, I guess I would just say that I would favor including, intragastric balloon with sleeve, endoscopic sleeve gastroplasty given the lack of differential evidence between the 2. We're not comparing to head to head, but they're saying that we both have evidence, the level of evidence is similar for both of them, so if we're going to include one, I think we should include the other. Thanks.
Valerie King	Yeah, this is Valerie King. If you wanna go ahead with your conversation, I'll scan down through the report, but that bullet point that you were referring to that was a really high level summary came from the executive summary. And I believe that there's a little more nuanced information in the main report, but I'm trying to scroll down to it right now.
Sheila Rege	So, why don't we, Jonathan, wait for that? Let's have Janna and Christoph had questions and then we'll go back.
Janna Friedly	Great. I, I was gonna go back to the previous conversation about the mental health evaluation and comprehensive. I, I think we might be able to clarify a little bit and, I apologize, I'm having difficulty coming up with the right words, but with a cover with conditions to me, it doesn't make sense just to say metabolic and bariatric surgery accreditation and quality improvement program accreditation. Because that doesn't

tell you what that means. So I think it's what we're trying to get at is that you should have a comprehensive evaluation and treatment through a program that is accredited, and that could, you know, should include, should be a comprehensive evaluation that includes addressing any contributing you know, mental health conditions or, nutritional evaluation as appropriate or something along those lines. I'm not speaking articulately, but.

Sheila Rege — There is, there is something, Janna that I texted, somebody, in California, girlfriend of mine who does very, actually, and she said something about a participation in a multi-disciplinary surgical preparation program or something. Judy Chen may have better, but I like what Josh did. He put it on the bottom. Did you see that? HTCC encourages appropriate mental health, the valuation of support as needed. I just wanna let them know that that's covered in case, you know, and we are, I mean, the agency is encouraged.

Janna Friedly — Yeah.

Sheila Rege — But I hear, I mean, we could say comprehensive multi-disciplinary evaluation or number of, what do you.

Janna Friedly — Great, I think the way it is now with the note, I think is Okay. I mean, put the note right or right.

Sheila Rege — Okay.

Janna Friedly — With the comprehensive evaluation and treatment so that it's linked.

Sheila Rege — Yeah, I just want everybody know it's covered and so if you know

Janna Friedly — Hmm.

Sheila Rege — So you go to that, Janna. So, let interrupt us, we can go back to Jonathan's question, Christoph.

Janna Friedly — Yeah.

Sheila Rege — Dr.Lee?

Christoph Lee — Oh yeah, I was actually gonna get back to Jonathan's question as well. I had the same issue I guess with gatric balloons, if you look at the effectiveness data you know, gastric balloons had 2 RCTs, SADI-S which we are including at 0 RCTs. And when you look at the safety profile, gastric balloons had lower deaths than SADI and EGB. It seemed to have lower rates of re-operation, readmission, and ED visits than many of the surgeries were including. So both from a cost or from a clinical effectiveness and safety profile, I feel like gastric balloons should be included. It's just that 2 out of the 3 cost effectiveness analyses included IGB or focused on IGB but it could very well be that the others have no, not a great cost evaluation, but they just weren't evaluated

	from the cost perspective. So just based on clinical effectiveness and safety data, I also don't see a difference between IGB and other surgical interventions. So my question I guess is for Dr. Judy Chen, do you feel that IGB is a routine gastric bypass procedure that should be included in this list?
Judy Chen	Looking at kind of how the days going specific to data efficacy. You know, I think it is effective for weight loss but that's the part that I really want to that I see is not in the literature is that it's the long term, the years and years out because it is removable. So yes, it is effective against nonintervention in that 1st year, when the devices in the stomach for 6 months and then afterwards it's removed. But I would say that as a surgeon and someone who really knows as long-term complex always sometimes relenting disease. The long term part of that, I don't know. And I don't wanna overstate any sort of cost effectiveness of that. So. I don't know that answers your question, but that's my honest opinion. And that's why like the balloon compared the gastroplasty is different.
Christoph Lee	Right. So yeah, I guess, I guess.
Judy Chen	Loon is something that's removable gastroplasty staying and so that's that long term so I.
Christoph Lee	Right, right. You have mentioned that it's used as a bridge for some individuals to try to get their weight down so they could get one of these permanent solutions or procedures. By not covering it, are we taking away that bridge?
Judy Chen	Yes, I think that there is a possibility of taking away the bridge to transplant to orthopedic surgery for more mobility and then better outcomes of that to previous surgeries that you're unable to have another operation, there are certain conditions that you can't bariatric surgery. So, intragastric balloon does have bridge place so that not why is not just purely a high BMI, it can be in many areas of BMI that can last under a second operation or second treatment.
Christoph Lee	Thank you.
Sheila Rege	So. Is the committee's wish to exclude intragastric balloons or included? Do we need a vote on that? Laurie, were you gonna speak on that?
Laurie Mischley	Yeah, just on the same topic, the other thing that did come up once before is there is a subset of the population who is drawn to the fact that it is reversible. Who is not want a permanent surgery but does want help. And so I do just wanna, I would vote to keep that option on the table for the bridge for that subset of the population and to trust that the surgeon will help the patient navigate what's best for them.
Sheila Rege	Was there a reason we originally excluded it? Was it? It wasn't the scope of the study. Was there a safety issue or something, why, why we excluded it? Ask you.

Judy Zerzan-Thu	This is Judy Zerzan-Thul and I made these draft criteria and I excluded it because of the lack of long term evidence because it's just a short procedure. So that's why it was not on here to start with.
Sheila Rege	Okay, so it's just not long term. But it was discussed in the studies, right?
Valerie King	It was assessed in the studies. This is Valerie King. Although the follow up on those is generally at 6 months. We have years to follow up on other procedures, most of them.
Sheila Rege	What does the committee wish to do? Take a vote? Okay, or let's do a just don't don't do a real look just a straw pull up. We can see each other raising our hands or something to see if we feel it's okay to keep it in. Janna, are you going to speak on this?
Janna Friedly	No, I was gonna speak on something else.
Sheila Rege	Okay, so is does anybody have great heartburn about putting it as an included procedure. If you do raise your hand now, otherwise it will go. Laurie doesn't like it in included. No, you can only raise your hand if you object to it being moved into included. Tony is raising his hand. Anybody else? Okay, Tony, go ahead.
Tony Yen	My concern is that the long term issue. That Judy Zerzan-Thul has raised.
Jonathan Sham	I just want to point out that's by nature of the technology, it is intentionally short term procedure. I mean, there are no long term outcomes because it's not meant to be a long term fix.
Tony Yen	Exactly. I think you and I are on the same page a little bit. Jonathan?
Jonathan Sham	You wouldn't have a long term outcome for this technology. Just based on what it is. So I guess saying there's no long term data doesn't really make any sense to me. Let's say there's no long term data for like a haircut. Like, yeah, it's just something that's short term by nature. So again, if there's a clinical indication for something as a bridge or short term or whatever and it's efficacious and safe, it should be evaluated on some merits, but to say that doesn't have the same longer efficacy, it just It misses the boat, I think given what the procedure is and meant to be, it's not meant to be a long term.
Tony Yen	And I agree and well, I guess I'm framing this within the context of the other procedures that we're evaluating over here. I almost wanna just completely set this procedure aside as something completely different that you know if there needs to be something for a bridge I don't know there's a difference for procedure for that I guess I'm what I'm thinking about are these procedures in the context of a more should I say a more kind of like durable solution for the longer term.

Christoph Lee	Just to respond to that, I guess went into bullet point for comprehensive evaluation treatment plan and the accredited center cover that, they, we go over the options that are more permanent and suggest those, but if for some reason the person needed a temporary bridge for it whatever reason that's indicated it seems like it's safe and effective.
Sheila Rege	I, I can tell you I almost voted like Tony and the reason is I don't know. I don't think you have like those liners and they have so many temporary procedures to help patients to lose weight. I liked it being non covered. I don't think I have heartache. I think it comes. But. Judy, Dr. Zerzan-Thul, there wasn't any safety things that you that you for flagging, it was more just a duration issue?
Judy Zerzan-Thul	Yeah, there is no safety concerns with it.
Sheila Rege	Okay.
Jonathan Sham	Well, I think Tony brings up a great point. Like, if we think there are distinct inclusion, exclusion criteria, it's because it has a different utility and use, we should separate it out. I just don't think it should be eliminated whole hog forhe reasons we discussed.
Sheila Rege	Well, if it is a temporary procedure, then I think putting some guardrails, you can only have it once every so many years or something. I mean, I, you know, it's meant to. If we are gonna keep it in. So should we officially take a vote on that since we are a little bit split? Let's do a vote on including intragastric balloons moving into non-cover can you do a.
Laurie Mischley	Before we take a vote, can I just clarify, didn't I hear that it was less than 1% of the procedures that we're talking about. Am I remember remembering that number correctly? A really small percentage.
Sheila Rege	But that's good. But is that because it's not covered? As soon as it's covered, it'll go up.
Laurie Mischley	Oh, I see. Okay.
Sheila Rege	And my, it's just a bugaboo. I just, you just don't want somebody putting that in and then you know 6 months. Oh I want to do with my daughter's wedding and then take it out and then oh I want to do it for this, a 1 time. So can we take a vote of If majority, I just wanted majority of us will process are okay with including that into procedures. I don't want this going down just because somebody had a heartache with just that. Are you able to?
Val Hamann	Would, are you okay if I just read down names and people can say either include or exclude and I can mark that down.
Sheila Rege	Yes. That's fine.

Val Hamann	Okay. Clint Daniels.
Clint Daniels	I'm still a little bit confused before I vote. For Judy Chen, how is this typically used as a bridge or that's just a possibility? And then how often are these repeated?
Judy Chen	It's a possibility. Let the historical is that before GLPs, there was not really great treatment options for someone in a BMI of 25 to 35. Because medications before GPS didn't make a difference. So at the endoscopic balloon allow for kind of that ability to provide some weight loss. Your second question. I'm sorry, I forgot.
Clint Daniels	Yeah, or is this something that's typically done more than once?
Judy Chen	The FDA approval, I think there is some words there about how often it's done, but no, typically it's not done more than what's in the United States. Internationally, it cn be done once.
Clint Daniel	Gotcha. Okay, so hearing it's, you know, typically done just a single time. I'm okay with keeping it in.
Val Hamann	Friedly.
Janna Friedly	I don't feel strongly one way or the other, so I'm a little on the fence here, but I'm gonna say exclude.
Val Hamann	Chris Hearne.
Chris Hearne	I am comfortable including it.
Val Hamann	Conor Kleweno.
Conor Kleweno	Include.
Val Hamann	Christoph Lee.
Christoph Lee	Include.
Val Hamann	Laurie Mischley.
Laurie Mischley	Include.
Val Hamann	Sheila Rege.
Sheila Rege	Include.
Val Hamann	Jonathan Sham.

Jonathan Sham	Include with conditions.
Val Hamann	Okay, Tony Yen.
Tony Yen	I actually agree with Jonathan on this one. I would include with conditions and that would be different from all the other procedures that we're discussing.
Val Hamann	Okay. So we only have one exclude.
Sheila Rege	Okay.
Janna Friedly	Well, I didn't know that that was an option to include with conditions. So I'm going to, since I was on the fence for that very reason. So.
Sheila Rege	Yeah, so if we include conditions. Who brought that up Jonathan what condition would you add?
Jonathan Sham	Well, I did, I said that as a half joke based on Tony nice discussion. I mean, yes, if. Based on the evidence we have, there are definitively different indications. Like what Dr. Chen was saying, we should call that out separately. And again, the data we have here is a little bit broad. It says 30 to 50 with or without comorbidities. So if Dr. Chen can give us some more nuanced approach that we find, you said about tolerance to medications, everything bridging to, you know, not safe for another surgery and to bridge something like that as comes to mind. But you can come up with if you can provide with any other kind of details on the current clinical use, the data to me provided to us seem to say that it's safe and effective. I just don't know what that is.
Judy Chen	So I think, the, the FDA, I can't, I am trying to look it up right now, but in regards to oh, I think it is good to think about if it is something that's so I guess so intragastric balloons are a little bit hard because they, they have so many different types. So the ones that are endoscopic to place and then endoscopic to remove, the ones that are swallowed and then endoscopically removed and then I think that there are some potential one that are swallowed but then excrete out the bottom and then there's even another that's gonna come potentially that's adjustable. So, I know this look a little quagmire of different types of balloons. And so I don't know if that makes a difference, but ultimately, I don't have any specific clinical guidelines other what you said Jonathan, actually pretty well Jonathan is you know, this is kind of because there's a contraindication for another more durable option. Or there's you know a reasonable why that, that temporary nature of the balloon is more ideal for that patient. So I think maybe those are the broad ways to say it.
Sheila Rege	When was the intragastric balloons introduced was it just recently? Was it like 2020?
Judy Chen	Technically, 1995, but those are the very old ones that had not the spherical shape, but the more recent ones with FDA, not the spherical shape, but the more recent ones with FDA, 2012 or 13, I think.

Jonathan Sham	Just for some context, if it's helpful, the ASGB bariatric endoscopy task force and HG Technology Committee and ASMBS clinical issues committee cite intragastric balloon therapy is an option for patients with BMI greater than 27 they say here in the United States or sorry 27 in Europe or 30 in the United States who have tried and failed previous attempts at weight management with lifestyle changes alone. That's all they say. They don't get more specific than that. It remains open whether integration, therapy should be used alone sequentially or with concomitant therapies as a bridge to bariatric surgery or others surgeries. So not much direction there.
Christoph Lee	I just put Dr. Judy, Chen, would you say that this is sort of a long lines of adjustable gastric bands which are in the vast minority of procedures or like, where would you put this in terms of use and popularity?
Judy Chen	Goes back to what's covered so it's not covered so right now it's not being used.
Sheila Rege	I'm just looking at the Cleveland Clinic website and it says insurance does not cover so I think.
Judy Chen	Okay, but I think that, you know.
Judy Zerzan-Thul	Yes, many of the guidelines and the coverage policies that we looked at for commercial, they view it as experimental. And so, they don't cover it. And I don't know the details of why they consider it experimental.
Sheila Rege	Yeah, I'm just now finding so. I think we should maybe keep it back on non-covered under this policy. And then can we ask the agency medical directors to come up with something for them with language just for intragastric balloons, would that be acceptable to the committee to move forward? Because I see us spending a lot of time without a lot of knowledge, I don't and I don't know if it's called out in the studies, Laurie.
Laurie Mischley	Well, I feel like we just took a vote to include it or not and we voted to include and.
Sheila Rege	I agree, but they're going to come up with language now on what the conditions would be so we could put that in a special coverage decision just for intragastric balloons. That's what I was looking. You want to keep it in here?
Laurie Mischley	I feel like that's our job is to do that here. I mean, my vote would be that we make a decision and not.
Sheila Rege	Okay.
Laurie Mischley	Kick the can down the road.
Sheila Rege	So we would be FDA condition or balloons. I'm looking for then what to put in there. Because that's the only one that has conditions, everything else is just covered.

Laurie Mischley	But the idea of including conditions is just an idea that we're kicking around. We don't need to make conditions. We could sit. And we should, you know, anyway, it's just all discussion right now.
Jonathan Sham	And, there are conditions for the other procedures the listed above.
Sheila Rege	Right, but do they apply it to the intragastric balloons? Or are we asking for more conditions for the intragastric ballons? Is my question.
Jonathan Sham	I think that's what we're kicking around right now.
Josh Morse	It seems like it sounds to me listening to this conversation, it's a different procedure. For a long term problem, but it only has short term data and it's reversible, it sounds like a different procedure.
Judy Zerzan-Thul	This is Judy Zerzan-Thul, I'll just say the FDA approved conditions gets a little tricky. We ran into this with cochlear implants. Because the FDA can change and that is sometimes hard for our contractors to keep up with. And I think the FDA approved conditions is for weight loss. And so that's the condition for these other things. So I'm not sure that that is the best part of language for this.
Josh Morse	I'm putting, I just put it in there as a placeholder having heard.
Judy Zerzan-Thul	Yeah.
Sheila Rege	Somebody help us move past this because I'm okay with working on it if we want to, but it always seems like a separate cover. We'd have this, but then we'd add more stuff if that's the will of the committee
Christoph Lee	So am I hearing. Yeah, doctors using told that you think that gastric balloons are not gastric bypass. Is it? Because this this entire topic is gastric bypass surgery, but this isn't Is a balloon not considered desperate bypass surgery?
Judy Zerzan-Thul	Yeah. It is, this is Judy Zerzan-Thul. it is considered gastric bypass surgery and so that's why it's in this review. I think the thing that makes it different is the, the long termness, because it's not long term and obesity is a complicated issue that is for sure a long-term issue, even after you've had surgery or one of these condition, you know, one of these procedures, like it's not a magic thing that suddenly you don't have to think about your diet, you don't have to think about anything else. Obesity tends to be a lifelong struggle for folks. And so, in thinking about obesity in that context, it just really felt to me like the balloons were short term and, we're likely not helping anything. Again, thinking in the context of, of the space of obesity right now, we do have the GLP1s and those can help some people lose weight. You know, you could argue whether those should be short term or not, or you needed something as a precursor or a bridge, I think could be filled by medications. None of that is in this report. So I think that part is hard to say, but, I guess I'm thinking that if you all feel

really strongly that it should be in here, I think, putting it in, as It's hard to say. Some of this is medically necessary, but maybe putting that time stamp on it as Sheila said that you get this once every 5 years or something so that it wouldn't become something that you were using as sort of a main way to try and lose weight over time because this is really, this is a very short-term procedure and the rest of these things are longer and obesity in general is a longer term thing. I guess that's what I'd say.

Christoph Lee — To respond to that, is there any way to frame our decision that this coverage is for long term solution? if that were the case and I'm fine leaving it out. But, and we're not really looking at other short term obesity measures or medication. So it Is there a way to make this coverage decision about a long term solution for obesity with gastric bypass procedures.

Judy Zerzan-Thul — This is Judy Zerzan-Thul again, I, I don't think so because of the scope of what was reviewed. I don't know if we've done that before, Josh, sort of excluded something that was in the review or, or sort of changed it, but we didn't put a time stamp on the kinds of procedures we looked at and the kinds of evidence that we looked at. So I, I think that makes it a little more difficult.

Josh Morse — I think so too, but I think you could write criteria for it, you know, I agree with you, Judy. I don't think you can exclude it from the scope. But I think you could write criteria perhaps. Or you could choose.

Judy Zerzan-Thul — Yeah, Dr. Chen, what? What do you think about this? You know, this is your field. What do you think would be helpful and evidence-based?

Judy Chen — I guess I'm also getting a tiny bit unfamiliar with this particular section of the committee's work. So does it go on later to, to have some of the indications contraindications later or is that left up to clinicians? Because as a person who performs this operation, we have such a variety of different insurances and coverage and on coverage that dictate that, so I wanted to ask a question. And if it was included in here, who later gets to decide those details?

Judy Zerzan-Thul — So this is Judy Zerzan-Thul and these would be the conditions that would make the medical necessity review. So, as it's currently written, we don't have any exclusion criteria in terms of these patients can't have this or, you know, it's more, it's currently framed more in the positive of who can have this with rather broad brush jokes left to the clinicians. I will say this committee doesn't always do that. And so, it depends, but I think the piece that you know, I'm wondering if this will help us get unstuck if you could help us, you know, tell us where. If you had a magic wand where this procedure would fit and be helpful or is it because the GLP1s around that maybe this doesn't have that short-term role anymore. I think that's the piece where, we're asking, I think.

Judy Chen — All right, so that clarifies. So. In the scenario. If I were to look at a patient and say we would like you to have a different operation. What's, what's a very safe way to do it. The medications, let's say, takes a year for someone to lose, a couple of months of

	weight with medications versus the balloon. The balloon and medications and might actually be cheaper to go with the balloon, because it's maybe just one endoscopy. In regards to where would I use this in my practice there are definitely patients who I think could benefit from a balloon even though it's not completely long term because And again, allows them for a orthopedic operation and thus improved nobility and thus and contribute to, treatment of obesity and also fits into where someone would be very comfortable with having this type of option that's removable or reversible. There's not a lot of it going in right now because it's not covered, but if it was covered, I think there would be quite a lot of people very interested in this type of therapy option. Did I answer all of the question?
Jonathan Sham	Dr. Chen, what would be you say this typically happens once in a patient's weight loss journey. What would be like the minimum amount of time you can imagine between 2 balloon placements if a patient were to have that for some reason? They get it for their knee surgery, then they needed to get in for something else.
Judy Chen	All that data is international. I'm not very familiar with it. They're the only thing that I can think to respond to that I also answers the question is that once the balloon is removed, you do want to wait 6 months for the tissue to actually remodel because performing a secondary bariatric operation is a little bit higher risk than the balloons in place because it does actually make some changes to the stomach tissue. So if I were to again have no evidence, but maybe just go off of that, I would say having it only once a year would be a good time stamp. That's what the studies are balloons over 6 months and then for 6 months, they continue the comprehensive care with the team and the dietician and all the other portions of lifestyle change. So it's usually meant for like a 1 year and that's how every study usually balloon patients forward.
Jonathan Sham	Is there precedent for having approval this is for Sheila, Josh, Judy, is there precedence for having approval contingent upon like a plan for after the procedure technology. So we'll do the balloon as long as you have a plan for long-term weight loss after that. I'm trying to think of how we could put some guardrails on it, if it is truly in intended to be a bridge either you have a surgery scheduled or you have a plan for X, you done anything like that in the past?
Judy Zerzan-Thul	Not in my tenure here. I think it's hard to make things conditional on a plan for the future because you, you know, it's easier to say no to things on the front end. You know, will people really follow through with that plan? You've sort of lost your ability to, do that. I guess I'm thinking of my kids in screen time if I give them screen time right away they don't do their chores. And so I don't think we have any wait to make sure that plan is followed, but that being said, I don't know that I'm opposed to having some plan and that can be reviewed for medical necessity. To see if it seems like it's a reasonable plan. Yeah.
Josh Morse	Yeah, I have a, I have a thought. I think what's not known is I again as I listen to this what's not known is what is the long term value of this procedure, which is what you're being asked to consider, right? You have a temporary procedure for a chronic

condition and you're trying to figure out if you if you cover this and it sounds like there could then be quite a deluge of, of access, because it is it sounds like it's far less permanent invasive however you want to say it. What is the result of that? You don't know is what I think is happening. You don't know what the long term result of a decision like that is, on utilization, on health outcomes etc. It sounds like there's quite a bit of information perhaps missing to answer this question about when to use this and what happens if, If it's covered.

Sheila Rege — Shannon and then Laurie.

Shannon Robalino — It's Shannon Robalino again. I just wanted to point out that in the 2015 criteria there is a bullet point in there that says when covered individuals must abide by all other agency surgery program criteria. For example, specified centers or practitioners pre-operative psychological, evaluation, participation and pre-operative and post-operative multi-disciplinary care programs. So you have some of that language, the current criteria.

Valerie King — Okay. This is Valerie King and I also want to draw your attention to Appendix M. This is an appendix, it's long, it's over 130 pages. But it's all FDA MAUDE database reports of. Device problems, recalls, injuries, malfunctions, etc, this 130 plus pages is all about balloons. Now they're there because they're a device, so they're gonna show up in this MAUDE database in a way that surgeries won't. But I just wanted to highlight that for you in your safety considerations because you're spending, you know, time thinking about these devices.

Sheila Rege — I'm looking for help in moving us forward. I see this this intragastric balloon as totally different than everything else. So that was my 1st suggestion. We pull it out, put a separate coverage policy for it, with conditions and then vote on that. Rather than having it get us stuck on what the other stuff, but if people wanna keep it here, then we're gonna have to either decide like Dr. Zerzan said once every whatever years? 5 years, one year or surgical plan, we're gonna have to come up with something. And. Yeah, so I'm looking for one of the committee members who's helped me out before help me get out of this pickle.

Jonathan Sham — I think the timer strain is a reasonable mechanism to achieve what we're all wanting to achieve and that's not over utilization. Dr. Judy Chen, I mean, I'm just in kind of, I realize every patient is different, but in kind of real life practice, can you imagine a patient realistically needing one more than every 3 years? Or a bridge to something or for achieving a particular weight lost goal for another procedure. I just threw out 3 years just little out of a hat, but realistically speaking, like, you know, when you're seeing these patients who need to get a need done or to get or wanting get to another bariatric surgery. What's kind of the real world frequency?

Judy Chen — Yeah, I think, anything more than a year, 2 years, 3 years are all pretty reasonable. I definitely not less than one year. So maybe just to make it easier. You know, for 2 years, every 3 years same to me. I guess, you know, it's, it's, it's trying to really

understand the patient's goal. And there's a variety of types of centers and so I think, it could be something where the longer year might be better because It's, it's important to make sure that you know we're not maybe are you trying the same treatment that actually doesn't really fit that patient, you know, to get coverage. So maybe, like you said, even 3 or 5 years is probably, going to be the better versus 2 years. So that's I think about it.

Clint Daniels — I thought you said earlier that it was something that was typically like once in a lifetime. So I'm, I would definitely be more comfortable with a longer timeframe than a shorter one, if we're gonna consider that as a condition.

Judy Chen — I don't think. It's a lifetime because it just is not covered so it's never died. I don't know what it means. I don't think I meant to say that so I wanna make sure. But that was not what I meant or said

Janna Friedly — Sheila, what would it be you know, after having her this discussion, would it be helpful to just take it one more straw poll on where we're standing with this in terms of including excluding or, or cover non cover, cover with conditions or cover with these current conditions or cover with different. You know, pulling it out.

Sheila Rege — You mean just the intragastric or everything?

Janna Friedly — Yeah, no, just the balloons, intragastric.

Sheila Rege — Intragastric?

Janna Friedly — I don't know. Looks like Laurie and Conor are. Yeah. There's been a lot of information that has.

Sheila Rege — Yeah.

Janna Friedly — New information that has been provided. That I think is. Maybe that doesn't help.

Sheila Rege — I would be in favor of that but I've got 2 more hands up so let's see if they can help us move forward. Laurie?

Laurie Mischley — I just wanted to add one more thing. I mean, we're talking about the long term effectiveness of weight loss, but I, I work with patients who have malabsorption and malnutrition syndromes with neurodegenerative diseases. And admittedly, we haven't done much nutrition follow-up. We know we are putting people at increased risk of malnutrition with a bunch of these surgical procedures. And the entire science of nutrition is so in its infancy and our appreciation of the long-term impact of the malnutrition syndromes that we will probably be causing with some of these procedures has not even begun to be studied in the way that it should be. And so I think if we're, I loved that doctors as then took some time to talk about the long term cancer outcomes, long-term mortality, really kind of thinking through the downstream

	consequences. And I just like the idea of if there is a person who wants to do something that's a little temporary and not put themselves at a but risk of a bunch of long-term malnutrition problems that they're going to be dealing with for decades. I don't want to remove that option from somebody. I don't care if it's a once in a lifetime thing. I just, I hate to remove the option because I think we're not thinking through some of the long-term nutritional outcomes of some of these surgical procedures and that needs to be considered for me.
Sheila Rege	Conor
Conor Kleweno	Yeah, I have a 1 question, one suggestion, my suggestion is we either just vote on it and move on or we say not cover and can revisit this as the was mentioned there's 24 other studies coming on in the future this is a device so I know that that's gonna have a lot of advancements new devices coming on the market and so more information for this type of procedures gonna be coming out in the future. So those are my suggest we do one of the 2. My question is just because we've been spinning for a while. I can't remember. Other coverage, entities on this, on intragastric balloons, Dr. Chen was saying it's not covered. That's why it's not used to remind me private payers, Medicare, all that stuff. I just, I can't remember who's covering it and who's not maybe we can use that as a, as a guide.
Judy Zerzan-Thul	Yeah, this is Judy Zerzan-Thul here's the table and no one covers it. That is the answer.
Conor Kleweno	Okay, so if we were voting to cover it would be different than everyone else out there again that may be fine. I recognize that but just want to remind the panel of that. And I think we should do one of the 2 things.
Sheila Rege	I'm gonna take a prerogative of the chair and in light of everything being discussed, let's take another straw call of just intragastric balloons whether, oh, sorry.
Val Hamann	And would, would you like that as either include or exclude or would you like that as not covered, covered unconditionally or covered with conditions, which way?
Sheila Rege	Yeah, 3 choices. That people just wanna actually just to exclude in this policy or include with I think the only guardrail I'm hearing is a time guideline once or something once every 5 years like Judy Zerzan-Thul. So let’s give us a choice.
Val Hamann	Okay, perfect.
Sheila Rege	Covered, bring it back down to non-covered or keep it in covered and we continue the discussion.
Val Hamann	Okay. We'll start with it Conor Kleweno.
Conor Kleweno	Cover.

Val Hamann	Christoph Lee.
Christoph Lee	Not cover.
Val Hamann	Laurie Mischley.
Laurie Mischley	Cover.
Val Hamann	Sheila Rege.
Sheila Rege	Not covered.
Val Hamann	Jonathan Sham.
Jonathan Sham	Cover
Val Haman	Tony Yen.
Tony Yen	Not covered.
Val Hamann	Chris Hearne.
Chris Hearne	I'm a little bit torn, but I think not covered.
Val Hamann	Janna Friedly.
Janna Friedly	Not covered.
Val Hamann	And Clint Daniels.
Clint Daniels	Not covered.
Val Hamann	So you have 6 as non-covered and 3 cover.
Sheila Rege	And when are those studies going to come out so we can, we can re-look at that? Or maybe we'll get a request just to do that.
Shannon Robalino	Hi, it's Shannon. It looks like the majority of those ongoing studies, excuse me, there are 4 of them that include intragastric balloon as a comparator is one of this to a surgery, RCTs. And then there is one that's a nonrandomized study. And if you give me just a moment, I can look to see when those are due, so there is one small randomized study comparing an adjustable intragastric balloon, the SPATS 3 device, the non-adjustable device that Dr. Chen mentioned that there were there are some that are actually adjustable that completed in July of 2022, but we didn't identify any publications related to that one. And the non-randomized study is looking at the Obelon device endoscopic sleeve gastroplasty and lifestyle interventions and that one

	has just completed in March or specified that it was competing in March. And I think there are.
Sheila Rege	On the most of all coming out this year like September and July at 25. So that we should, we should have enough data that we can look at it soon again.
Shannon Robalino	Okay. So those are the completion dates, so you need to add probably one to 2 years before we see publications on those.
Sheila Rege	I have been reminded that I have been, that not giving us a break. We've now, I think, finished. Let's look at the guidelines. We finished adult. We still need to move, work on, adolescent. Maybe we could take, how, I open to how long we want for a break because our staff are really they can't even go, you know, leave. Do we want a 5 min, 10 min, 15 min? What does people want? 10 min. 5 min break and in the meantime when we come back we'll project let's start with the agency medical directors recommendation on adolescent. And we'll project this so people can look at it. Consider this your 5 min break to look at the policy. Thank you guys. Let's see you in the 5 min. I think it's been 5 min. We'll wait for people come back. So that's for adults. And can we move on to?
Josh Morse	Well, we
Sheila Rege	Oh, does it? Does it say, oh, yeah, we adolescence. Okay. With bone maturity and with one obesity related complication. Is everybody okay with that? Is there anything else we need?
Conor Kleweno	Laurie has her hand up.
Sheila Rege	Oh, sorry. I don't see that, Laurie.
Laurie Mischley	Yeah, just back to the malnutrition thing. I think though one anastomosis bypass has the greatest risk of nutritional deficiency syndromes and the studies I saw on adolescence did not include that procedure. I don't know if anyone can clarify. I don't want to start getting into nit picking, but I am concerned about malnutrition in developing kids. Would there be a reason to go there? I mean, does the evidence suggest that procedure is appropriate for adolescents?
Judy Chen	Take all the studies. Oh, sorry, Shannon. Oh yeah.
Shannon Robalino	This is Shannon. Oh, go ahead. I was gonna say that those are, they don't look at that procedure in children. It's not, currently one that's done for children in children. It's Roux-en-Y, sleeve gastrectomy, or adjustable gastric band.
Sheila Rege	Dr. Judy Chen, would you like to comment before we go on to?
Judy Chen	Oh, Shannon said exactly. I was also gonna say that gastric bypass and sleeve are the operations for adolescence.

Sheila Rege	So we'll have to add that in.
Josh Morse	You wanna add? Go ahead.
Janna Friedly	But that's the best that we have a separate, have a separate coverage conditions for out specifically for adolescents.
Sheila Reg	That's what I was originally thinking, but. I think Josh was trying to put it in here.
Josh Morse	This is, this is how we, this is where we started from. So,
Sheila Rege	Right, right. Can we make it work by keeping it in here with an asterisk? And then on the bottom say the only approved procedures for adolescents are blah blah blah. That would be easy.
Josh Morse	Do you want to say this is limited to adult patients?
Sheila Rege	No, you can put an asterisk on adolescence. We wanna put an asterisk there. And on the bottom notes adolescence or the only covered procedure for adolescents would be what did Dr. Judy Chen say.
Judy Chen	Sleeve gastrectomy and Roux-en-Y gastric bypass.
Sheila Rege	Laurie, would that address the concern and good pick up on the studies? I wanted Josh if you said are the only covered procedures for, adolescence, you know, just make it very clear. Laurie, is, is that good? Okay, and then we had another hand raised.
Laurie Mischley	Yeah, that's great.
Sheila Rege	Okay. Christoph.
Christoph Lee	Oh yeah, just in terms of the bull point, there for adolescence, I would change with one obesity related complication to with at least one obesity related comorbidity. And that would mimic the language in our prior decision.
Sheila Rege	And adolescence do we, do we, what we already say encourages mental health. So hopefully the physicians will encourage adolescence to go for that nutritional support. I don't think I wanna prescribe it, but in regards to Laurie's concern, I think, the nutritional support more. Anything else there? Anybody else's hand raised? If not, are we? Good with taking a final vote. Any more discussions or we are okay with taking the final vote? Let's move on to a final vote.
Val Hamann	Okay, and like before, make sure you're in ttpoll and again we've lumped these together for adolescents and adults to view this as written. So would you like me to

	share that slide or would you like to look at, have these up on the screen kind of so you can see both.
Sheila Rege	I prefer seeing both if possible.
Val Hamann	Okay. Okay, so. That poll is live.
Sheila Rege	They sign me out. I need to get back in. Sorry.
Josh Morse	So should I stop sharing, Val?
Val Hamann	No, you can still share because it's as written so they can view that.
Janna Friedly	Well, I'm having trouble with the poll. It locked me out and when I logged back in it says, message unknown polling type. Anybody else was having.
Sheila Rege	No, I, they're letting me in. I had to I had to read
Conor Kleweno	Yeah, just close out, Janna and try to re-click the link and log back in maybe.
Sheila Rege	Oh no, you're right, it does. It did say unknown polling type.
Janna Friedly	Let's do the whole thing.
Conor Kleweno	Yeah.
Sheila Rege	I'm gonna close it on and start again. You are in Conor?
Val Hamann	Yeah, I have 7 votes right now.
Conor Kleweno	Yeah, I'm in. I had, I had to close and re log in, but just takes one click. So.
Janna Friedly	Okay. There we go.
Sheila Rege	Okay. Okay.
Val Hamann	Okay, we have them all. So we have 9 votes to cover as written for adults. Then we'll go into adolescence. And we have 9 votes to cover with conditions as written for adolescents.
Sheila Rege	Okay. Moving on if we go to the next agenda item, Josh, that we have to do.
Josh Morse	Thank you. So you've completed the vote. You have voted to cover conditionally for adults and adolescents. Is that correct with the conditions as written that we were looking at?

Val Hamann	Correct.
Sheila Rege	Correct.
Josh Morse	So, we then need to check the, for Medicare national coverage decisions and guidelines.
Sheila Rege	And this will have to change SBRT for you to bariatric surgery.
Josh Morse	Yeah, I think that's a typo. I apologize. This is just a reference document that I'm using here. So.
Sheila Rege	Okay. And I think we've already discussed that because we have that table.
Josh Morse	You did pour over the guidelines, that's right. Let's see if there's a Medicare. So it appears you are consistent with this requirement for using accredited centers. You have maybe selected a different accreditation method, but you have talked carefully about that. I don't see a problem of being looks like you're aligned with this NCD.
Sheila Rege	Good. We can move on.
Josh Morse	So that concludes the bariatric. Melanie, do we have discussion about scheduling? Or a debrief from today's use of the new technology?
Melanie Golob	What, were you thinking for scheduling?
Josh Morse	Okay, I think we reserve some time to potentially talk about attendance. We've had some attendance issues lately. We've talked individually with a couple, clinical committee members whose contracts need to be reupped, not about anything specific or related to their attendance. I guess one thing I would, I would ask for your feedback on is, you know, if there's new challenges with scheduling. We have the opportunity perhaps many months from now to have a retreat. And talk about this and talk about virtual versus in person meetings. I think for our team one thing that's super important is to know when a meeting time won't work for you as much in advance as possible, we've had some challenges with. Being sure that we have enough people to, you know, have a functional meeting with a quorum. And certainly we like to have a meeting with more than a minimum number of members for that. So. I don't know, Dr. Rege, do you have anything to add about, about that.
Sheila Rege	I actually had suggested that at the, meeting at the, what do you call it? The yearly strategic session that the committee look at. A. whether continue virtual versus any person that being the 1st decision and the second decision being whether we should have minimum meeting attendance, be it, pick a number. A lot of my committees have that. I think it's 75% for a lot of, a lot of my committees. And we try and make that because that is becoming more of an issue today, I think. I know John Bramhall told us

it could be at it very early and we still continue the meeting and I think he's the only one missing right?

Josh Morse — We have a new clinical committee member, Dr. Michael Leu, we had hoped would join us today, but then he apparently had a last relatively late conflict with being able to attend today. So yes, we do currently we have 11 members. And Dr. Bramhall and Dr. Leu could not be here today. And we, you know, I don't think we have people that are at or below 75%. I think we just have had some unfortunate convergences in the past year where a number of us have not been able to attend. But again, it's not a consistent problem. I'm not I don't want it to seem that way. I think it's just really important that we talk about it and make sure that we are doing what we can for you to be able to fully participate and we did talk about alternative days. I think we'll just need to continue having this conversation, but if people have ideas right now, I think we have a few minutes we could. We can hear what your thoughts are.

Sheila Rege — Is Friday still good for most people? Yeah, it's hard because I know Jonathan is like, well, any day is tough. I think the other thing, It is, let me, sorry, is that today like, you know, we schedule it at 5 o'clock.

Conor Kleweno — Okay.

Sheila Rege — Sometimes we schedule it till 4, everybody's got something else to do. So I think for a staff standpoint, if you can schedule it for longer, that forces us in our offices to work around them. Somebody was, had something to say.

Conor Kleweno — I just had my hand up. So, I think all of us are gonna be different. Me personally, Friday's are tough. It's a academic and personal travel day often if I'm gonna go to a meeting if I'm gonna teach it a course it's usually you know Friday plus minus Thursday if I'm gonna go on vacation usually it's including a Friday so those days are tough. And then I would say, I don't know if I'm disagreeing with you or we're seeing the same thing on the duration. I would say one thing is that you know, a 9 h meeting is. That's a lot. I know today was we had some, you know, kind of things that we had to catch up on that, but you know, having a half day meeting is easier than a full day meeting. And so I just think a duration and you know, maybe that's part of just being more efficient, maybe this new technology can help with our voting. But I think one struggle I've had at least once, if not twice was The meeting scheduled, 3 or something, and we're still talking and debating things. I think that was the November meeting for me. So just to comment.

Josh Morse — Thank you.

Sheila Rege — We used to be able to do 2 topics at once and as things just got a little complicated I've been keeping it with one topic seems to. Oh.

Josh Morse — Yeah, so, that's a great. Yeah, so the June 14th meeting will be one topic with, we will ask you to consider a petition that somebody has brought to the Health Care

Authority, which is written again in the rules. The director did not select a technology that was petitioned for and the petition would like you have the final say in a situation like that where topics not selected that'll be the 1st item of business on June 14th And then we'll have whole exome sequencing. So is it best for us to schedule that as 8 to 5? No, it's really only one topic and it may be very possible that we you could be done at one or 2 or would you so schedule till 5 the whole day or schedule till somewhere like 3 and risk that if the topic runs long, we bump up against decisions you've made about what to do after 3. What's your preference?

Sheila Rege — My preference just because I keep getting a text if you do it to 3 is to keep it till the 5, but I'm open others. I think Tony, you had your hand up first.

Tony Yen — So my preference is actually to limit the time and actually that makes us have a little more discipline about staying on time. I can think time makes, like our task will expand to the time that we have allotted sometimes.

Sheila Rege — And if you do that, Tony, though what happened with, the last topic though the stimulators. We kept running out of time that we had to keep the can down so we needed just Let me say be discipline. We have to have a commitment then to finish it, like not schedule a patient at 3:30 if it's over at 3. I don't know, Conor, Clint.

Conor Kleweno — I think Clint is first.

Clint Daniels — I prefer the 8 to 5 scheduling with the chance of getting out early. I think kicking it down the road, I think it makes it so much harder to remember what happened in the prior meeting and come to the decision. So I would be in favor, for basically prioritizing the meeting for the day and then hoping to get done early.

Sheila Rege — Conor.

Conor Kleweno — I agree with Tony. I think we can, I think we can move along better, task expand with time give, I do agree with that. And if something is just, you know, out of the ordinary, complex where you know there's some issue we're having. I do agree with Clint it does make it more difficult, but I just an 8 to 5 day, is just I just think that's a lot to ask for people to commit to and I think that's a lot personally, but.

Sheila Rege — Johnathan.

Jonathan Sham — I agree with the shorter timeframe, but again, I don't think, I think an ounce of prevention is worth a pound to cure and I think it's about pretty cool in the future, limiting the scope of these discussions, you know, and I realize that's happens early very early in the process with the key questions but when you have something like SBRT with all of these different diseases, you know, or SCS, you know, again, we can control the length of the meeting again by not biting out more that we can chew very early in the process with the key questions in scope of the decisions, but again echo that 8 h is or 9 h is a very long time.

Conor Kleweno	And I don't try to qualify my statement. I'm not saying that we're lazy. It's just given that all of us on here have 1,000 other professional and personal things that that was all my comment that you know, one shouldn't be asked to work 8 hours, in here have 1,000 other professional and personal things that that was all my comment that you know one shouldn't be asked to work 8 h. Just in the context of everything else.
Janna Friedly	I don't think anybody would consider you lazy.
Sheila Rege	No. Did that help you? Josh and your question.
Josh Morse	Yeah, I've heard 3 people say limit time. I've heard 2 people argue for scheduling the whole day. I guess I'm gonna, maybe split the difference with our team and we'll schedule, block out till 2. In I'm open to other suggestions will schedule 8 to 2 that will provide the opportunity maybe for 5 h for one topic. Let's assume that we ate up the 1st hour with this conversation a previous meeting business and but we will plan to not have to use all that time. We'll be more efficient to the degree that we can. Does that sound reasonable?
Sheila Rege	Yes. And I do want indulgence of the committee members that are almost there you try and stay like you don't plan something for 10 min later, you try and give a little buffer like you're running late in the clinic. You give it a good half hour more.
Conor Kleweno	Is it? I'm sorry to do my hand, but, Josh, is there a way, like, for example, this, this petition we have to review. Can we hard limit that? Cause you know, sometimes I've seen we sort of get going and we're already delayed before we get into the topic. But like for example, this petition, you know, we're gonna just give it half hour one or whatever it is and if we don't finish it that gets tabled to the next because we are we need to get on to the topic of the day for the 5 h.
Josh Morse	Yeah, I think that's a great point and I will defer to you and the chair and the vice chair on how, how you want to do that. We will provide you with the petition in advance. We don't plan to have a presentation about this. You, you will receive a petition 2 weeks, roughly before the meeting on June 14th The instruction to you in the emails that we will send will be to that you know we you will be asked to decide and it could be a simple vote to rereview or not rereview based on the petition to rereview that topic and you know it could be 15 min or less. I don't think there's a lot that needs to happen around that conversation.
Sheila Rege	So should we give it 15 min? We give it 30 min? What do you want to get it? You've seen the petition, I have not.
Josh Morse	Yeah, no, I think it's, I mean it's 15 min I think if you read if you look at the petition prior to the meeting and have formed your opinion about whether the evidence presented could change the previous determination. That's the question at hand. And you know, that's the one, the petition, I would say, 15, maybe 20 min, the other, that,

	is reminding me of is you'll have 2 decisions to go over any comments received for spinal cord stimulation and for bariatric surgery and then minutes so there's likely or action items in the previous meeting business, you know, all told, I can't predict how many comments might come in on those 2 new decisions. The minutes usually take a couple minutes to discuss. So I would suspect it'll be less than an hour for previous meeting business could be wrong. I hope I didn't jinx it.
Sheila Rege	Alright, anything else?
Josh Morse	Not for me, no. Super appreciate your time and all the effort today on these 2 topics. So thank you very much.
Sheila Rege	Thank you, guys.
Val Hamann	That's Tony does have his
Josh Morse	Oh, sorry.
Sheila Rege	Oh, I miss that. Sorry, Tony.
Tony Yen	So, I want to agree with Conor. If we can just be, I think really kind of clear about how much time things are allocated and having that discipline and also that sense of urgency in the beginning of our meeting. Sometimes I feel that takes a little while for us all to get kind of wound up a little bit. But having kind of that sense of, you know, time is, an important resource of all of us and having that urgency as we trying to stay on time, that's all.
Sheila Rege	So what I would love, Conor and Conor is a ringleader there and Tony, I would love for you to inject in there. You know, we, we're a little late. We only, we only have an hour, feel free to come on because that helps. Can't just be the chair kind of saying that so. You guys can be my timekeepers. Is that okay?
Conor Kleweno	Yeah, thanks, I appreciate that. I appreciate that, you know, so as we don't feel like we're overstepping our bounds or being rude.
Sheila Rege	No, that'll really help if you can come in and say, guys, you know, we were already 1:45. And just having more voices there. For all of us as committee numbers will really help. So Joshua, my name, we've got a new like a timekeeper kind of role with Tony and Conor.
Conor Kleweno	Yeah.
Tony Yen	Sure, and I want to do that respectfully.
Josh Morse	Sounds good.

Washington State Health Care Authority

Conor Kleweno	Yup, thanks.
Sheila Rege	Anything else otherwise I would love to adjourn.
Josh Morse	You're good to adjourn.
Sheila Rege	All right. Take care. Bye.
Laurie Mischley	Thanks, everyone.
Josh Morse	Thank you.
Christoph Lee	Right.
Tony Yen	Thank you.