Washington State Health Care Authority

Washington State Health Technology Clinical Committee Meeting

Stereotactic Body Radiation Therapy

May 19, 2023

DISCLAIMER

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Val Hamann (HCA)	That has started
Sheila Rege	Welcome everybody. Um, and maybe we will start with roll call of the committee members just to test everybody's microphone. And ensure we have a quorum after which we are going to do it a little different. I am going to be chairing just a portion of the updates, January meeting minutes, and our previous business of the Transcranial Magnetic Stimulation. After which, Janna will, uh, chair today's meeting. Melanie, can we help with quorum. Can you read off names so we can test our mics?
Val Hamann (HCA)	Yes. Larry Birger. Jonathan Bramhall. Clinton Daniels.
Sheila Rege	I'm sorry, I just wanted people to say yes, just so we know they are there, testing mics.
Jonathan Sham	We can't hear you, Clint.
Sheila Rege	We can come back to Clint.
Val Hamann (HCA)	Yeah, uh, Janna Friedly.
Janna Friedly	Um, present.
Val Hamann (HCA)	Chris Hearne, Conor Kleweno, Christoph Lee
Christoph Lee	Present
Val Hamann (HCA)	Laurie Mischley.
Laurie Mischley	Present
Val Hamann (HCA)	Sheila Rege.
Sheila Rege	Present

Val Hamann (HCA)	Jonathan Sham
Jonathan Sham	Present
Val Hamann (HCA)	Tony Yen.
Tony Yen	Here.
Val Hamann (HCA)	Okay, so we know Clint is here, but um, potentially having some issues with being able to talk so
Sheila Rege	How many committee members were unable to unmute and speak? 6?
Val Hamann (HCA)	6, yes.
Sheila Rege	Okay, and we will wait for Clint. Um, so the motion we need quorum for would be the January meeting minutes. Um, do you want, do you feel comfortable, Josh, doing the HTA program updates while Clint is trying to get back on or figuring out why he can't unmute.
Josh Morse (HCA)	Um, yeah, that's fine Sheila, we can start with that.
Sheila Rege	Go ahead.
Josh Morse (HCA)	There we go. Great, welcome so this is the May 19th, 2023, Health Technology Clinical Committee meeting. My name is Josh Morse, I'm the Program Director for the HTA program here at the Health Care Authority.
Melanie Golob (HCA)	Josh, I think the one is sharing is uh..
Josh Morse (HCA)	The main one? Interesting, where's that
Melanie Golob (HCA)	I think, that's uh…
Josh Morse (HCA)	There we go. Make sense.
Melanie Golob (HCA)	Yeah.
Josh Morse (HCA)	Thank you. So um obviously if you're seeing the screening we have started the webinar here. We are using Zoom today and will be switching to Zoom on a more permanent basis, so the Zoom controls if you're not familiar, there are different ways to address your audio settings and raising your hands and there is a Q&A function, some of this we will be using today. So as Dr. Rege pointed out, and our agenda was up there briefly, we will start with previous meeting business from the March meeting and then scheduled for today is a review of stereotactic body radiation therapy. All of the materials for today's meeting are available on the program website, which is at hca.wa.gov and following the links to our health technology assessment program in today's meeting. This meeting is being recorded, a transcript will be made and then published on HTA webpages. When participating in discussions, please state your name and um, use your microphone so that we can hear you and the transcript can be accurate. A little bit about the program, the

health technology assessment program is administered by the Washington State Health Care Authority. This program brings evidence reports to the Health Technology Clinical Committee to make coverage decisions for selected medical procedures, tests, and devices, based on the evidence for safety, efficacy or effectiveness, and cost-effectiveness or value. Multiple state agencies participate, to identify topics, and implement policy decisions from this process. They include the Health Care Authority through the Uniform Medical Plan and the state's Medicaid program, the Department of Labor and Industries, and Department of Corrections applies these decisions as well. The state agencies implement the determinations from the clinical committee within their existing statutory frameworks. The purpose of this program is to ensure that medical treatments, devices, and services that are paid for with state health care dollars are safe and proven to work. This program provides a resource for the state agencies that purchase health care and through this process we develop scientific, evidence-based reports on the medical devices, procedures, and tests that are selected. We support the HTCC to make determinations for these selected, um, technologies, based on the best available evidence. There's multiple ways to participate and again this information is on the programs webpages. You can sign up for notifications from our program using the agencies GovDelivery process and there is information on that, um, from the webpages. Anyone may provide comment on proposed topics, key questions in the draft form, and on the draft and final reports, and on the draft decisions. Anyone may attend these HTCC public meetings and present comments directly to the committee on the day of the meeting. Anybody may nominate topics, technologies for review or rereview. For public comment, attendees who are scheduled to provide public comment will be temporarily reassigned as a panelist here in Zoom and provided the option to unmute and turn on their camera if they want to. Um, when we do this, a pop-up window will ask you to rejoin the meeting as a panelist. There will be a slight delay when that happens. Please limit your comments to four minutes or as otherwise determined in conversations with our program specialist. When you are finished providing public comment, your role will revert back to attendee, there will be a pause in the meeting while you rejoin. If you're not signed up in advanced, please indicate your interest to provide comment today using the chat function before the comment period. And the volume of signups will determine the available time for each person. We have a 40 minute period available for public comment today, if necessary. We ask that you please disclose any potential conflicts of interest prior to making your comment. And again, for the record, we ask that you clearly state your name, if you can please share any conflicts of interest that may be appropriate. This is a public, there, there, we will show this slide during the public comment period, but this is the, the public comment portion of the meeting which will occur here in a few minutes. Yeah, these are the rules for public comment. So, uh, this is the agenda for today, again, previous meeting business, and then the review of SBRT and then following in that order, we will start with the agency medical director's presentation, we will then have the public comment period, the

	evidence report will be presented by our contractor, Technology Assessment Center. There will be a Q&A portion for the committee with the evidence vendor and there will then be a discussion and decision-making. Future HTCC meetings. The meeting after this, the next scheduled meeting is in July, the third week in July, and scheduled for that meeting is review of hyaluronic acid and platelet rich plasma. The status of that report right now is that we're in the public comment period of the draft evidence report. The next scheduled meeting beyond that is November 17, 2023 where spinal cord stimulators will be considered. And we are in the public comment period for draft key questions for that report right now. Uh, finally, after today's meeting, if there is a draft decision for SBRT today, we will publish that draft determination for a two week comment period. Uh, and that concludes. So if there's any questions right now, we can entertain those about any process issues. Thank you.
Clint Daniels	Josh, real quick, can you guys hear me now?
Josh Morse (HCA)	We can hear you now, Clint, thank you.
Clint Daniels	Thank you.
Sheila Rege	Are there any questions for Josh? And, uh, so we will let the record indicate that we uh now have seven members present. And uh, let us move on to the January meeting minutes for approval. Uh, I believe this was one, Larry, you were not present at the January 27th, so um, we will have others who were present, um who were present make a motion for approval. I'll, I'll wait for that.
Clint Daniels	So moved.
Sheila Rege	Can you put that on? Thank you, Clinton.
Laurie Mischley	This is Laurie, I second.
Sheila Rege	Okay. Any discussion?
Josh Morse (HCA)	Okay.
Sheila Rege	If not, let's vote for the meeting and I would like to use this as a process issue, how would staff like that. Would you like us to go A or would you like it in the chat? What works best?
Melanie	I think we have a poll for it
Sheila Rege	Okay, we are going to put a poll for it. I just want to test it out while this is, ya know, uh, early in the day so we know how to go for it. And if you have the poll for the rest and you just want us to say A for this, that's fine too.
Josh Morse (HCA)	Uh, Val, do you have a poll for the minutes
Val Hamann (HCA)	Yes, pulling that up. Are you all able to see that?

Sheila Rege	Thank you, Val. Yes.
Laurie Mischley	It says
Sheila Rege	I can't click on it
Laurie Mischley	Yeah, no. Host and panelist can't vote.
Val Hamann (HCA)	Oh, sorry. Yes, okay. Sorry, hold on. There was a
Sheila Rege	Thank you, Laurie.
Val Hamann (HCA)	Sorry, let me relaunch this. Okay, you should all now be able, have access to that.
Melanie Golob (HCA)	A reminder this is just.
Val Hamann (HCA)	Okay, it looks like we have seven votes.
Josh Morse (HCA)	Uh, we had maybe one extra vote and not a committee vote. Christoph, did you recuse yourself from this?
Christoph Lee	I did. Yeah abstain from voting.
Josh Morse (HCA)	So for the, the voting today, when this comes up on the screen, we, we are working with the Zoom polling, if you are not a committee member, we ask that you please not respond to the poll if it appears to be an option for you, the voting will just be for committee members. So, I think, if Christoph, you did not vote, we will need to redo the vote. Or maybe we should. Or maybe someone can say they voted if they are not a committee member.
Val Hamann (HCA)	Not everybody has access.
Sheila Rege	Not everyone can speak. They probably can't speak. Do you want to redo it Josh, so we, we can make sure. I just wanna, ya know, test this process out before we go for actual votes.
Val Hamann (HCA)	I can easily relaunch if you would like that Josh
Janna Friedly	I, I think
Josh Morse (HCA)	No, I think
Janna Friedly	Is, is there, there is no ability for the host to see who, who has voted, um,
Laurie Mischley	Might be an advantage of using the chat?
Janna Friedly	I have a little bit of a concern for the actual voting part if we aren't able to tell who, who has submitted the votes, um and if there's a possibility that, that anyone other than voting members can submit by accident, then we can't tell
Val Hamann (HCA)	Yes we can pull the, after, after the poll has closed, then we can uh pull the, um, responses from the browser which will give us an excel spreadsheet so

Sheila Rege	Janna, you're going to run the meeting topic, so how would you like it. We are trying this poll and if we have that ability we will redo it and then see. But it did worry me, I would have expected only 6 votes
Janna Friedly	Yeah and I think given the number of votes that we going to need, ya know, this is a more complicated topic, um, with more votes then some of our others, that um that if its, if its um, takes awhile to close the poll and then get the excel spreadsheet to double check I worry about time. That's my only concern.
Val Hamann (HCA)	And I do have that up so I can see who voted. So.
Janna Friedly	Okay, okay. So we can try this if it, um, if it works this way, if it seems to be taking quote a bit of time, we may need to go back to the chat voting
Josh Morse (HCA)	Great. Thanks Janna, thanks Val. I thought the voting was limited to panelist so but it doesn't appear to be that way so maybe there is something working properly.
Melanie Golob (HCA)	I think it is, I think we got it figured out, we got it figured out who the extra person was so…
Josh Morse (HCA)	Okay, thank you. So, um minutes are approved from the previous meeting and I think we are ready to move onto the decision, is that right Melanie?
Melanie Golob (HCA)	Yes. Yeah so um, can everyone hear me okay, if not I um…
Janna Friedly	It's ah, it's a little faint.
Sheila Rege	Our agenda said after that we would do future meetings, is that just confirming dates for the record?
Melanie Golob (HCA)	Um, next up is the previous decision.
Val Hamann (HCA)	It..
Sheila Rege	Okay.
Val Hamann (HCA)	It looks like this is, nevermind.
Josh Morse (HCA)	Can you hear Melanie? Melanie can you speak for a minutes
Melanie Golob (HCA)	Yeah, Dr. Chen said no, so.
Janna Friedly	Little faint.
Laurie Mischley	Sound a little far away.
Gary Franklin (L&I)	Very hard to hear.
Melanie Golob (HCA)	Okay, can you hear me better now?
Val Hamann (HCA)	You have an echo.
Melanie Golob (HCA)	Yeah. Okay, how's that? Okay, so can everyone hear me better now?

Sheila Rege	Yes.
Melanie Golob (HCA)	Oh but then mine is muted. Okay. Okay, there we go. Everyone can hear me?
Sheila Rege	It's perfect.
Melanie Golob (HCA)	Okay, thanks. Okay so next we will review the previous findings and decision from the March 17th meeting on transcranial magnetic stimulation. We received a number of comments so let me scroll down to those.
Sheila Rege	So, it should be in your packet and it, it for everybody, I believe, its page nine.
Melanie Golob (HCA)	Yes.
Sheila Rege	No actually its page 11.
Melanie Golob (HCA)	You should also see it on your screen. We received two comments suggesting some changes so I'll pull up those on the screen.
Sheila Rege	Thank you.
Melanie Golob (HCA)	And suggesting a number of uh sessions.
Sheila Rege	So to summarize what I saw on my initial review we had said 34-36 sessions and they say the common is 36 and they would also like um the first commenter uh who is um Regence Blue Cross Blue Shield a supervisor would also like a uh discussion about failure defined more specifically a 50% reduction in symptoms. That's the first commenter. Uh, the second commenter summarize, we will bring it up on the screen, also had the 50% reduction uh saying that the standard threshold for repeat um and also um want, uh, uh, wanted more clarity on what we mean by minimally clinically important difference I think they just want 50% which is apparently a standard according to the second person too and the second person is a behavioral health medical director. Um, and then the other clarification that was asked for is the severity of depression, uh, can the be incorporated into treatment resistant depression, is this limited to moderate or higher severity. If we could pull our language that we approved so we can look at it in light of the suggestions and again if anyone wants to look at on the big pdf its page 8 and page 11. Thank you. So, um.
Melanie Golob (HCA)	So.
Sheila Rege	Would anyone like to so anyone want to comment first on the number of fractions, what we had compared to what was in the letter?
Melanie Golob (HCA)	Yeah, Sheila we can pull up the suggested edits in the language. We started mocking up uh what the changes would be.
Sheila Rege	That would be helpful.
Melanie Golob (HCA)	Okay, great.
Simon Lo	Excuse me, I saw antidepressant on the screen, am I in the right meeting?

Janna Friedly	Yes, we are discussing our previous meeting decision from the last meeting umm.
Simon Lo	Oh okay.
Janna Friedly	It is part of our process before we start on the new topic.
Simon Lo	Yeah, sorry, I got kicked out of my office, uh, and I had to find another office to do the meeting.
Janna Friedly	Oh yeah, no problem.
Sheila Rege	Yeah this usually takes a very short time and I apologize I did not introduce you because you're gonna get introduced when we discuss today's topic and Janna's gonna chair that. So um.
Melanie Golob (HCA)	So, we have.
Sheila Rege	So are we going to try and incorporate that and see if people would like that in there?
Janna Friedly	So I think Sheila what I am trying to grapple with going back to understand, um, where the 30 treatment sessions came from to make sure we are not just reacting to something without the, the, uh, was not consistent with the data that we had available, um, and understand that so, um.
Sheila Rege	I think we had had up to 30, correct, in the original language?
Janna Friedly	So we have up to 30 but the suggestion is to modify that to 36, is that, am I understanding that correctly?
Sheila Rege	Right.
Janna Friedly	So.
Sheila Rege	34-36, um, and I uh, I tried to pull the original, um, the PDF from the original meeting to look through that and ya know on our studies and I think that was something we talked to the clinical expert but somebody else help me with.
Janna Friedly	Yeah, and that's what I am see that I think it was 30 came from, uh, 5 treatments a week for 6 weeks, for 4-5 weeks, was a typical period, um, and that they felt that was generous, ya know, that many, many or most patients did not require that much and that 30 was on the older devices that was studied on the initial FDA labeling, um, sometimes 30 is needed depending on the device but so that was, um, I think driven by our clinical expert. From what I can tell, but
Sheila Rege	Right.
Janna Friedly	But I can tell if that was the standard, um in the evidence.

Sheila Rege	But then we've got um, uh, ya know, uh, insurances company who are currently paying for this that what they are seeing is a request for 36 and, um, and I don't want ya know, that, if that's what's been commonly done in the, the um field, um.
Janna Friedly	Umm-hmm.
Sheila Rege	And, and I don't know. I'm looking, I'm looking for guidance from others besides just Janna and me, on whether to restrict that or whether we can say up to 36?
Tony Yen	Sheila if if if our review, this is Tony by the way, if our review had shown that up to 30 is actually what the literature supports or and what our clinical expert has supported, my tendency is to go with that instead of necessarily what the insurance companies do.
Sheila Rege	Right.
Clint Daniels	Yeah, I am, quickly.
Sheila Rege	Any other discussion?
Clint Daniels	I'm quickly reviewing our transcript from last time, and it looks like our expert did say it was based on, uh 5 treatments a week for 6 weeks, is where that number came from.
Sheila Rege	Thank you, thank you for that clarification. And just for the record, let's just name on name, Sheila Rege, thank you for that.
Jonathan Sham	Hi, Jonathan here, ya know the message from Blue Cross Blue Shield says that most provider protocols do 36 sessions, I mean, is it possible to actually see those protocols to better understand them to have a little more granularity or is that something we have to decide on right now?
Sheila Rege	Sheila here, I don't know if we can um get that information, unless staff feels differently?
Judy Zerzan-Thul (HCA)	We could ask for the plans that we are contracted with for Medicaid and for our employee and retiree benefits, this is Judy Zerzan-Thul.
Sheila Rege	Sheila here, now do we, does the committee what to hold off on a decision on the 30, or the 36 until we have that data and maybe we will get that later today?
Janna Friedly	This is Janna Friedly, I would feel more comfortable having a little more data before we make that decision because it is not consistent with what our clinical expert provided us and, uh, I am trying to reconcile that with what the literature and it's a little bit challenging to do that so I think having a little more evidence before we make the decision would be my recommendation.
Sheila Rege	Okay, so on that issue, but I would like to flush out the other two issues too, in case we need a little more clarification, the other two. The next comment was uh, uh a definition of failure and I know we discussed it during the meeting, um, and came

	up with our language so let's see, let's see what can we project our language with the proposed change and see what the committee feels about that and if there's a more clear definition on 50% reduction on symptoms?
Melanie Golob (HCA)	Okay, can you see the sharing I am doing right now of the edits in the Word doc?
Sheila Rege	Yes.
Melanie Golob (HCA)	Okay great.
Sheila Rege	So we said 30% or more improvement and I don't remember any data, we, we kind of struggled with that. Does the committee wish to change that to 50%?
Jonathan Sham	So um, Jonathan here, just to recap here just so we are on the same page here, my recollection that 30% was chosen as the MCID for the HAMD instrument so that's why we chose the 30% and then this email from Tawnya Christensen says just 50% is standard threshold for response so it seems like we're just kind of comparing the kind of agreed upon MCID for a specific instrument versus kind of what is being told to us as standard I guess my in the absence of other data I guess my impulse is to stick with the MCID that we previously agreed upon that is published and.
Janna Friedly	And I, I think as this is Janna Friedly as I'm reading this too we, we had included the, the MCID of 30% or more for the repeat TMS but the they comment is related to the, initial treatment so if we were to be consistent with the initial treatment and repeat we would use the 30% improvement as a definition of failure or lack of getting you know below 30% as, as, as a failure if we needed to define that and I think we, we also discussed it at length whether we needed to be more specific or if this was one of those cases where it would be preferable for us to leave it at the discretion of the, um, the treating provider to define failure.
Tony Yen	Yeah, this is Tony.
Sheila Rege	Yes, okay, go ahead. Janna, also in favor of leaving 30% is that what I'm hearing?
Janna Friedly	I, I am for, for the, the repeat and then I, I think we still on the table is whether to clarify what the failure of at least two different antidepressant medications is if that is less than 50% improvement or less than 30% improvement or, or to leave that open if I if we're going to specify I would keep it consistent with the initial and repeat which would be 30%.
Sheila Rege	Tony, Tony? Thank you, Tony go ahead I wasn't looking at raised hands, this works just informally I'd like to continue that go ahead.
Tony Yen	Sure, so I agree with Jonathan and Janna's opinion of just sticking with the 30%
Sheila Rege	OK so let's stick with 30% unless there's somebody who has feels differently on the repeat would anybody want to clarify the initial you know failure two different antidepressants believe it like we have do we want a definition there what failure is?

Tony Yen	This is Tony I think we should just leave it.
Laurie Mischley	This is Laurie, I agree.
Jonathan Sham	Hello Jonathan here, so just to clarify it looks like this kind of revised document removed the MCID verbiage from number 3 for repeat um just kind of a question it seems like we chose 30% because that was the specific HAMD MCID but again there are other instruments used which 30% may not be the right number did we still want to keep that language in there to allow people to use other instruments and if so I guess would it be worth just adding that to the initial number one on the initial language as well since we're using the same idea?
Sheila Rege	Just talking about what we've deleted in number 3 the deleted words being or minimally clinically important difference?
Jonathan Sham	Yeah just I suppose a reminder of why we had that in there initially it's because it was to allow for the use of other depression scale indices, it, from my recollection, and if we remove that I guess 30% is not pegged to, to the GDS and the PHQ 9 that may not have an MCID of 30%. So just again, thumping on that, and then expanding to perhaps adding that to number one if we're going to stick with the 30% that number.
Sheila Rege	Jonathan that’s a good point. Any discussion? Sheila, this is Sheila asking. Any discussion?
Janna Friedly	Sorry just one other, this is Janna, one, one other comment about the, the reason one potential reason to leave failure a little bit less specific is that it may, may not be a failure based on improvement on a scale but tolerance to the medication and side effects so I think failure allows for other definitions of.
Sheila Rege	You're going back now to the initial let's, let’s, let’s keep it on the topic of that highlighted let’s project that again.
Melanie Golob (HCA)	Sorry I got kicked out of the meeting OK can you see?
Sheila Rege	Yes.
Melanie Golob (HCA)	Okay, great.
Sheila Rege	Yes, okay, great so Jonathan so you highlight the OR minimally clinically important difference so we’re still on the repeat treatment would people like to keep that in as we originally had it or would people like to delete that based on what Jonathan said?
Clint Daniels	This is Clint. I think Jonathan was arguing for keeping it if I understood correctly keeping the language in and I, I would agree with that based on his arguments.
Laurie Mischley	This is Laurie. I also think he made a great point and I suggest keeping it.

Sheila Rege	We're going to keep that then so we're not going to delete umm and there's everybody OK with 3.1 moving up the way the into two.
Melanie	Yeah, so it just switched these two is what that change was.
Sheila Rege	I don't see a problem with that. Would you like to accept all those changes just for repeat and so we can see that and then we'll vote on both eventually but let's just that's how it's going to read for repeat. but there's no further discussion on that Sheila again let's, let's go back and talk about whether to define failure or not Janna you have started that discussion on the initial treatment side of it.
Janna Friedly	Yes, I, I think I was I was just arguing that I, I, I would I, I would argue to leave it as is because tying it to, to solely to 30% or more improvement on a validated scale doesn't take into consideration that there may be other reasons why a treatment would be considered a failure.
Jonathan Sham	Yeah, it's a great point Janna I agree so.
Sheila Rege	Jonathan, anybody else?
Val Hamann (HCA)	It does look like Christopher Chen has his hand raised.
Sheila Rege	Thank you for telling me that. Christopher, sorry.
Christopher Chen (HCA)	Thank you I just want to because this was raised from the MCO during one of our meetings with them as well and I think there, um, was lack of clarity just on which thresholds applied to which instruments and so 30% on which scale or medically minimally clinically important difference on which scale and so I was just wondering if the committee felt like it was worth clarifying that in the language, um, really more like a grammatical thing than anything else and kind of the order of those bullets and which scales they pertain to.
Sheila Rege	Anybody.
Jonathan Sham	But just to be specific, Chris, are you saying to like list each scale and the MCID for each scale is that kind of what they wanted or is that the granularity they're looking for or something else?
Christopher Chen (HCA)	My understanding is that 30% of our improvement and sorry if I'm not following correctly 34% or more department applied to a specific scale or the minimally clinically important difference applied to a different set of skills should I get that wrong?
Jonathan Sham	Yeah, yeah that again that that was I think for the handy 30% specifically because that was really stated that it was the most commonly used scale but we did not specify GDS PDQ 9 all, all or PHQ 9 all those other all those individually is that what you think they're looking for.

Christopher Chen (HCA)	Yeah, so I think there's just kind of confusion and you know the words minimally clinically important difference could be confused for like the HAMD or like 30% could be confused for the other skills that the minimally clinically important difference is being applied to and so just maybe some specificity there might help for kind of actual.
Judy Zerzan-Thul (HCA)	This is Judy, I think it's maybe OK as is if we include the minimally clinically important difference which is you know maybe what one plan was arguing for because I think it does depend on the scale and but if you show a huge improvement in your PHQ 9 that's you know it's hard to get to an exact 30% but on that from that but if you do that then I, I think that's still a reasonable goal.
Sheila Rege	You're, you're suggesting leaving it?
Judy Zerzan-Thul (HCA)	As is I maybe I don't know yeah I guess I don't know why, why they feel like it's important to make this, um, really tight here, um, my sort of coming away from the last meeting was that TMS can be very effective for people with depression especially when other things haven't worked and so they wouldn't want to put a lot of barriers in place if this worked for someone when, um, when other things didn't yeah I don't know I guess some of it is probably how are they going to put their criteria in place and is there an easy checklist and maybe there's not an easy checklist with this minimally clinically important difference. Um, yeah, I don't know Chris you have other thoughts or Josh?
Christopher Chen (HCA)	Yeah and I, I don't think I'm at least what I heard there wasn't an intent to kind of keep it tight I think it was just for like what is 30% applied for what is going to be important difference and if, if 30% is just for HAMD and then minimally clinically important difference for everything else then that would just be a little bit clearer but I think yeah just kind of reflecting their concerns that discussion so.
Laurie Mischley	I think we I think what I'm hearing people ask for is either evidence of a 30% or more improvement on the HAMD or a minimally or just delete that and just say minimally clinically important difference on a validated scale right it's either I think the clarity that people are asking for is linking that 30% to what yeah.
Judy Zerzan-Thul (HCA)	And I think they all know this is Judy again they all know that that 30% is on the AMD from the literature and so that's what they're like super focused on but I don't know that they need to be super focused on that yeah so I don't know I was trying to think of is there a way I feel like the OR maybe capitalizing the OR you know that it could be either one I think that they're getting sort of hung up on the HAMD part of the evidence which, which is an important part and not everyone uses that scale so.
Jonathan Sham	So, I guess.
Sheila Rege	Go ahead.

Jonathan Sham	I guess or it's worth my would be if we chose 30% for HAMD you we might as well say it because I think Chris is right we're not it's not totally clear and then leaving the MCID on a validated scale to give the flexibility for providers to use other scales I mean I think just clarifies as Laurie said just clarifies what the intent of the of us including 30% was in the first place and it's consistent with the committees you know original plan.
Sheila Rege	Can you put that on it can you can you give us direction on where, where to add that for HAMD?
Jonathan Sham	Kind of yeah right, right, right where I think it's being typed right now, I think it's.
Melanie Golob (HCA)	Yeah, do you want me to spell out what that is I'm guessing HAMD is not going to be descriptive.
Judy Zerzan-Thul (HCA)	Just going to throw it out I think, this is Judy again, and it'll be up to us to make sure that folks don't say you have to use the HAMD or nothing and it has to be this or nothing because I think this conversation has been pretty clear that that is not the intent so.
Melanie Golob (HCA)	And what does HAMD stand for?
Judy Zerzan-Thul (HCA)	Who's the fastest Googler?
Jonathan Sham	Hamilton Depression, Hamilton, yeah you got it, rating scale, yeah.
Sheila Rege	And they'll capitalize the or, or you know what you do that's fine.
Clint Daniels	But I think Depression Rating Scale should all be capitalized too.
Melanie Golob (HCA)	So this whole part here.
Sheila Rege	Yeah each one, yeah each word in the scale should be.
Melanie Golob (HCA)	I said. And Sheila did you want to wait to vote on this until you got more information about the number of treatment sessions.
Sheila Rege	Well we haven't finished one more we have two more things to discuss so we've already decided on the initial treatment we were not going to define failure but then there was another question that was asked, uh, about whether we wanted to talk about the severity of the depression and I am going to read what they said umm related to both initial and repeat criteria is severity of depression incorporated into the definition of treatment resistant depression that is, is this limited to moderate and higher severity that was the question so we need to make sure we consider that comment and I am opening it up for discussion so if you could highlight where we had put in treatment resistant depression.
Melanie Golob (HCA)	OK and you're talking about up here?

Sheila Rege	Yeah. Opening it up for discussion for the committee level on that concern whether what we meant this is that?
Janna Friedly	This is Janna. I, I seem to recall and I'm, I'm trying to pull up our transcript to, to remember but that we had discussed this and felt that that this defined or this term was well accepted and I'm an understood and I think adding the severity of depression adds a layer of complexity in terms of operationalizing that and, and how you define that that I, I think would be challenging my, my inclination is to leave it as is.
Laurie Mischley	This is Laurie. My understanding is we don't we did not review mild or forms of depression this was the task and this is all that the data supported us making a decision on I would not feel comfortable changing that.
Sheila Rege	Anybody wanna speak in favor of changing it? This is Sheila again, again so what I would propose would be that the vote on the changes we have made and then we revisit it later in the afternoon if we get the 30 versus 36 so that'll make things go faster we'll remember what our discussion was.
Melanie Golob (HCA)	Okay, do you want me to accept these changes?
Sheila Rege	Yes, please.
Josh Morse (HCA)	So if I could make a comment about this session, this is Josh
Sheila Rege	You sound far away too.
Josh Morse (HCA)	How about now?
Sheila Rege	Perfect, thank you Josh.
Josh Morse (HCA)	So I've been reviewing the transcript related to the sessions question it is addressed by doctor Burns on page 16 of the published transcript which is on the website and I can share the link or I can show you but I'll, I'll read this part it says so 30 came from this idea of five treatments a week so that I could you know she's saying 5 treatments for six weeks five days a week Monday through Friday you know for four to six weeks with the tapering period and that was with the initial studies that allowed for the FDA labeling and that was actually on the Neurostar device this is Dr. Burns speaking so there was quite a bit of discussion about this and it is documented in the transcript I just wanted to share that with you.
Sheila Rege	So yeah, thank you Josh and that's, that's not I, I don't want to marry it with a 30 to 36 yet but can we accept all the other changes we have made I'll take a motion for that.
Laurie Mischley	This is Laurie I move to approve the changes that we've just made.
Janna Friedly	And this is Janna, second.

Sheila Rege	Any discussion? OK let's do a poll and again we, we are not opining yet on the 30 or 36 because the committee has asked for the protocol which I hope to have by the end of the day.
Val Hamann (HCA)	OK we have a poll for this and it would be looking at the current findings and decisions that are on the screen. OK we have 6.
Sheila Rege	Christoph is abstaining. So we are done with that part of it and then again we haven't done the final approval yet because we're going to revisit and don't let anybody forget at the end of the day that we need to go back to that 30 or 36 now I would like to move on to the topic for today. Hand the baton over to Janna who is going to chair this because I have indicated a conflict and I will not be voting and will not be participating in the discussion except to help with process issues if they come up.
Janna Friedly	Great, thank you. So maybe before we move on to the agency report and our public comments we could take a moment to introduce our guest clinical expert doctor Lo and, and then I also would like to ask for any new disclosures but let's, let's first ask Dr. Lo to introduce himself and if you could also include any financial or other potential conflicts or disclosures that would be helpful.
Simon Lo	I'm a radiation oncologist specializing in brain and spine tumors radiation therapy and yeah I have led down the SBRT programs and as free NCI designated comprehensive cancer centers at Fred hutch and case comprehensive Cancer Center in Cleveland and Ed James cancer hospital in Columbus OH state and SBRT for 20 years and so um yeah my air of interest and research this also an SBRT and I've been involved in and, and we'll let you know guidelines in SBRT and national and international professional organizations so I'll be able to contribute to this meeting. In terms of financial interest um I don't have, have any like industry relationship pertaining to SBRT right now and yeah I don't think there's any relevant conflict. Well the other thing is I am the national medical director of the distinction in practice and stereotactic radiotherapy for registration study in collaboration with American College of radiation oncology so that's the only thing but you know it's really have no financial interest I'm just like doing something it's like service I don't get paid or anything like that.
Janna Friedly	Great well thank you so much for joining us today we really appreciate your, your expertise and, and help with this topic um are there are there any other new disclosures from any of our committee members related to this topic and, and as Sheila mentioned I'm going to be chairing this section Sheila do you want to just say a word about why you're, you're choosing to, to not lead this meeting
Sheila Rege	Yeah so radiation oncology and I wasn't sure I'm past chair of the American College of radiation oncology and there was some discussion there about whether they were going to comment and I didn't participate but didn't feel comfortable I also serve on the board of a company that produces the radiation kind of safety devices for space and I not really clear but preferentially used in stereotactic was with

	others I don't think so but to avoid any proprietary Janna and I talked about me abstaining.
Janna Friedly	Great, thank you.
Sheila Rege	From the voting and, and the discussions I would like Janna though just for a bylaws issue just make sure we have Joshua points based on the number of people we have whether we do have a quorum given that I would be outstanding I would like that discussed,
Josh Morse (HCA)	Yeah, thanks Sheila. We reviewed the bylaws this morning we had some last minute attendance issues with one at least one committee member indicating yesterday they could not attend and we actually had a committee resignation yesterday as a person realized they could not attend and so we had two they could not attend as of just the day before the meeting so our bylaws allow for a quorum is half plus one in this case that would be 7 individuals and a person who recuses for the bylaws does count as a member of the quorum even if they are not participating so we are good to go there the committee can choose to reschedule if they wish to have more members present but it's not required for your bylaws you're good to go as far as the quorum goes and you know voting will be the members that are not recusing any questions about that.
Janna Friedly	Any, any concerns from the committee and moving forward today? Okay, great so, so with that I think we, we should proceed we are running a little bit behind time and so I want to make sure that we have a time for our report and then following the report we will have scheduled an open public comment where we will have speakers have up to four minutes to present and so I want to make sure that we have enough time for that so unless there's any other business I think we should move to the to the report.
Val Hamann (HCA)	And if while the Sophie is presenting could the attendees who want to present put that in the chat as that is now available to attendees as it was originally disabled. Thank you.
Josh Morse (HCA)	So I think we'll be moving to Dr. Miller's presentation Sophie are you going to present for your screen, screen or would you like?
Sophie Miller (HCA) (HCA)	My screen here the uh our new zoom platform sorry there we go all right how does that look for folks?
Melanie Golob (HCA)	Looks good.
Val Hamann (HCA)	Good.
Sophie Miller (HCA) (HCA)	Great. OK so I am Sophie Miller (HCA) I'm one of the medical officers here at the health care authority and as you all know today we'll be talking about SBRT. Um, I just wanted to start off by giving a brief review of radiation therapies in general to provide us with some background. So there are two types of general radiation therapies one is external beam therapy that utilizes a machine to aim high doses of

radiation at cancer cells. The other type is internal radiation therapy or the source of radiation is put inside the body seeds or capsules. SBRT is an external beam radiation therapy and SBRT uses imaging to identify in three dimensions a tumor or a tumor lesion and then targets very high doses of radiation using few fractions or sessions of radiation. So the sessions occur over one to five sessions at very high radiation doses being 6 to 30Gy and this is compared to other types of radiation that may occur over 15 or 30 different sessions. So this committee reviewed SBRT back in 2012 and in that decision SBRT was covered primarily for inoperable phase one non-small cell lung cancer. This decision also covered stereotactic radiosurgery which is a type of SBRT that is specific to the brain and the spinal cord and so that coverage decision also covered CNS tumors primary and metastatic as well as cancers of the spine and paraspinal structures. As part of that decision all evaluations for SBRT were recommended to include a multidisciplinary team with surgical input and that's known colloquially as the tumor board. At that time agency medical directors had high concerns about both the cost and efficacy of SBRT and medium concerns about the safety, so since then since 2012 our UNP or uniform medical plan Medicaid and L and I have, have used that prior decision as their coverage policy, that being SBRT for inoperable non-small cell cancer only stage 1. Since then the SBRT audience has evolved in the last 10 years. We have had two evidence searches one in 2016 and one in 2018 and during those reviews there was insufficient evidence to review for a new coverage policy decision. Now in 2022 to 2023 our new evidence report has more data that may suggest expanding use for coverage for different types of cancer. So we reviewed four key questions the first was is there evidence for effectiveness for SBRT and patients with cancers that are not currently covered. Two what are the harms of SBRT. Three what is the evidence for differential efficacy in sub populations and then four what is the evidence for cost and cost effective. So this slide represents the data from the agency both in terms of utilization and cost this is for SBRT only and doesn't include information on SRS or their relation to the brain and spinal cord. You'll see we have data from the year 2018, 19, 20, and 21 and across you can see the number of individuals during these years that received SBRT per year which was about 180 to 225 and you can see that those encounters ranged from 975 to 1300 encounters. And in the bottom two lines you can see the total amount paid for SBRT on the, the 2nd to the last row is the amount paid for SBRT alone and the third row is the amount paid for SBRT and other related procedures. So that kind of maxed out there at 1.6 million for a total of 5.8 million over the course of those years. This slide shows the cost per CPT code for both the Medicaid fee for service and the, the L&I program on the UMP data is confidential and not publicly available. So then moving into discussion about the evidence, I want to start off by saying that for each cancer type there was a different body of evidence and so this was a series of dedicated evidence reviews based on the cancer type. There were a limited number of RCT so only 12 RCT's in total which created a lower certainty of evidence and then each comparison group tended to be different in the studies, so SBRT and some studies was compared to conventional radiation in some studies SBRT was compared to medications etcetera. Outcomes

were also measured differently across the different studies, some looking at disease free survival some looking at quality of life. This led to some heterogeneity in the overall evidence so one of the key questions we had did address safety, as I mentioned before SBRT uses a very high radiation dose per fraction which requires very high precision and accuracy, the margin of treatment is measured in just millimeters. It also requires specialized equipment and specialized staffing. Despite these challenges SBRT is not associated with higher rates of toxicity compared to other treatment modalities and in fact the evidence shows that severe and life-threatening toxicities with SBRT are rare. Cost data was limited and of course also specific to cancer types and specific to which other treatment modalities were used for the comparison group whether it was medication or conventional radiation. There was one specific example for prostate cancer that showed cost savings and improved access to radiation treatment. So in the next few slides I'm going to summarize coverage from different payers, guidelines for SBRT, and cost effectiveness and then I will move into my recommendation. So you can see here that there are three different pairs that I'm going to present United, Aetna, and Cigna and the cancers are listed in the in the column on the left. You can see broad coverage for all payers for prostate cancer, lung cancer, pancreatic adenocarcinoma, cellular carcinoma, as well as all of the metastatic disease. For the other cancer types kidney cancer, adrenal, head and neck cancers and bone cancer there is limited or no coverage for these cancer types. So this slide presents the full name for each acronym that I'm going to present in the following slides, I just wanted to give people a chance to look over these since I'll be using the acronyms only I will particularly be presenting information from ASTRO and NCCN. ASTRO the American Society for therapeutic radiation oncology and NCCN as many of us know is the national comprehensive cancer network. I see a chat is there something I need to respond to now?

Val Hamann (HCA) No you're good.

Sophie Miller (HCA) Thanks. So moving into the professional society guidelines, the first ASTRO and NCCN and then other professional societies and you can see here that for prostate cancer SBRT is recommended for low or intermediate risk prostate cancer and some other higher risk groups by the ASTRO and NCCN, as well as other organizations. For non-small cell lung cancer that's primarily recommended for early-stage inoperable non-small cell lung cancer by both ASTRO and NCCN. NCCN considers SBRT as a reasonable alternative to patients that are considered operable but very high risk for operation and then some of the other professional societies particularly those in Europe actually have expanded definitions to include up to stage 4 non-small cell lung cancer or stage 3A for those who can't tolerate or decline chemotherapy. For pancreatic adenocarcinoma ASTRO has conditional recommendation recommendations for use for resectable pancreatic adenocarcinoma only for multi-institutional clinical trials and then conditional recommendations for those that are borderline receptable. NCCN includes SBRT as an option for first line therapy for locally advanced disease or for those that are that are not candidates for induction

chemotherapy. And then moving on to hepatocellular carcinoma ASTRO for recommends SBRT for patients that are candidates for liver transplant or for liver cancer that's confined to the liver, and then NCCN recommends SBRT as an alternative to ablation or embolization, when those therapies have failed or considered contraindicated, or for HCC that consider unresectable, and inoperable. The other, for the other cancers, recommendations are either based on cancer type for oligometastatic disease or pretty narrow, so for kidney cancer, it may, NCCN states may be considered for medically inoperable stage one or stage 2 and then for adrenal cancer and NCCN states can consider for head and neck cancer insufficient evidence to recommend and then for bone and NCCN considers, states to consider for oligometasteses. There were no defined ASTRO recommendations for those cancer types that we found. So moving into cost-effectiveness. The data here was pretty sparse and specific to the cancer type for prostate cancer SBRT may be lower in cost than IMRT. It may be cost effective for oligometastatic disease, for lung cancer, considered possibly cost ineffective for maintenance therapy. For pancreatic adenocarcinoma, SBRT was found to maybe be higher in cost compared to conventional radiation. For the certainty of evidence, for this was very low for liver cancer, or hepatocellular carcinoma, SBRT was considered to possibly be cost ineffective compared to radio frequency ablation, however, cost effective for salvage therapies, and then, finally, for oligometastatic disease, the studies indicated that it could be cost effective with a moderate certainty of evidence. But I will qualify that that was based on modeling studies. The remainder of the cancer types did not have cost effectiveness data. So now I will move into the recommendations that we have. So for localized prostate cancer, the recommendation is covered with conditions. SBRT is a covered benefit for very low, low, and intermediate risk prostate cancer as defined by the NCCN criteria based on stage, Gleason score, and PSA. You'll see that second bullet which is to include a multi-disciplinary team analysis surgical input, that's a tumor board, and that's a recommendation for every cancer type here. So next, non-small cell lung cancer. The recommendation, again, is covered with conditions. The recommendation is to expand coverage, to include stage 2, a node negative it's non-small cell on cancer and continue to recommend it for medically inoperable patients or patients that are deemed too high risk for operative intervention or decline operative intervention. It's pretty clear from the evidence that SBRT is associated with worse outcomes than surgery for patients that are considering operable. For pancreatic adenocarcinoma, the recommendation is covered with conditions. Those conditions include locally advanced, pancreatic adenocarcinoma, and it is not covered for those with evidence of direct invasion of the bowel or stomach based on imaging due to the risk profile and again, tumor board evaluation for each of these cancer types. For oligometastatic disease, the recommendation is covered with conditions. The conditions include 3 or fewer metastatic lesions in a synchronous setting, appropriate imaging, demonstrating no evidence of widespread disease and a good performance, for as measured by a Karnofsky performance score greater than a equal to 60 or an ECOG less than or equal to 2. For hepatocellular carcinoma, the

recommendation is covered with conditions. Those conditions include 5 or fewer lesions, 6 cm or smaller, and a good performance status, or patients with unresectable or inoperable disease that are not candidates for liver transplants. They recommendation is that SBRT is not covered for treatment of the primary tumor of the following cancer types renal, adrenal, bone, small cell lung cancer, melanoma, multiple cell biliary track cancer, head and neck cancers, and then breast, ovarian, cervical, esophageal, and colorectal, and I starred those last 5 cancer types because they were actually not included in the new evidence report, due to lack of evidence overall. I will qualify this by saying SBRT is still a covered benefit for treatment of oligometastatic lesions. And I'll move on here to the last slide, which includes the summary of the recommendations included here. And then here is my information, if you have questions.

Janna Friedly Great. Thank you so much for that report. I would like to open it up to questions, for Dr. Miller specifically about her report, and maybe I'll start by saying that there was a question in the chat, and I had a related question about the cost effectiveness data I don't know if you can scroll back to that slide where you presented that, really quickly. Yeah, there, I had a quick question about certainty for prostate and lung. You have considerations there, but then certainty is not applicable, and I wasn't sure why, that was why there wasn't a low, very low, or low to moderate rating for those for the certainty?

Sophie Miller (HCA) I think I will have the center for evidence-based policy group comment on that because they are they are the group that evaluate the certainty for the cost effectiveness and I, I share the questions about that, because I think it was a little bit challenging to evaluate the certainty of the cost effectiveness data.

Janna Friedly Okay, that's great. We can hold off. And I think that there was another related question in the chat about what is meant by cost ineffective for maintenance therapy, so we, we can defer that.

Beth Shaw (CEbP) Okay.

Sophie Miller (HCA) I think that. Yeah, that was based on the specific study that looked at the SBRT versus maintenance therapy. Whatever the maintenance therapy was in that specific study.

Janna Friedly Okay. And then I'm seeing a number of questions in the in the chat. I think some of these look like they would be better suited for discussion after we have the evidence to report, and we can discuss with the clinical expert as well. So I, at this point, let's limit questions to Dr. Miller that are not specifically about the, the evidence. Are there any other questions from the committee? Okay. Great. Well, thank you so much for your presentation. I think at this point we will move to scheduled you open public comment, and again we are a little bit behind time, but we still have, I think, plenty of time for our comments and, as I mentioned earlier, I think we do have a few scheduled comments. We will limit these to format 4 min per presenter so that's we can have time for 4 min per presenter, so that we can

	have time for each of the presenters and as a, it when you are giving your presentation, if you could, first please introduce yourself and any disclosures, any potential conflicts of interest, financial or otherwise, before you give your presentation. That would be really helpful, so, Josh or Melanie, we have, do you have the list of the speakers?
Val Hamann (HCA)	So the yeah. So the first one that we have is Providence, Swedish radio surgery center and they will have, because there was a number of them who reached out, so they're pulling their time for 10 min.
Janna Friedly	Okay, great. And you'll be tracking the time and letting them know?
Val Hamann (HCA)	Yes.
Janna Friedly	Okay.
Val Hamann (HCA)	So I am promoting to a panelist now, so it may take just one moment and then they did have some prepared slides, so whenever they're ready to present that, they are ready. Dr. Loiselle, are you ready to present your slides?
Josh Morse (HCA)	Hey, Val, this is Josh. Can you hear me?
Val Hamann (HCA)	Yes.
Josh Morse (HCA)	We had one computer fail.
Val Hamann (HCA)	Okay. So I do, so, okay, so it looks like Dr. Loiselle may be having some issues with their mic and camera. So, is there anybody else? I do see Dr. Meier from your team. Is Dr. Meier have the ability to share?
Robert Meier	Yeah. Hello. This is Dr. Bob Meier. Can you hear me?
Val Hamann (HCA)	Yes, we can.
Robert Meier	Okay. Great. Thanks for the excellent presentation, Dr. Miller. I had a couple of comments about SBRT in the setting of prostate cancer and in the oligometastatic setting. One, first regarding the treatment of.
Sheila Rege	This is Sheila. Can Madam Chair, can we have a discussion on conflict?
Robert Meier	Oh, yes, sorry.
Sheila Rege	And stuff.
Janna Friedly	Yes. So I just wanna remind everyone when you introduce it. Please introduce yourself and any conflicts, and then, Val, that is this the part of the 10 min time period for this group?
Val Hamann (HCA)	Yes, I believe so.
Janna Friedly	Okay.

Robert Meier So I work at the Swedish radio surgery center and so we, we have a joint venture with Swedish hospital in treating patients with radio surgery and SBRT. I've also in the past received research grant in our institution for Accurray in a a multi-center SBRT study I did in prostate cancer. So, moving on regarding prostate cancer, I think you are correct and pointing out, there's good evidence in low and intermediate risks, organ confined prostate cancer that the treatment is, is effective and similar to external beam, as well as more cost, effective. In addition, there's at the NCCN points out that in high risk, patients in a setting where patients are, have difficulty or unable to come in for prolonged courses of treatment, that it's appropriate in high risk organ confined prostate cancer as well. So I think that that indication should be included. Regarding oligometastatic disease, you mentioned that it's appropriate, in up to 3 metastases as well as in this synchronous setting, but, but we, there's actually randomized data that, for example, a Saber Comet study included both synchronous and metachronous oligometasteses, and, and they also included up to 5 metastases. This is for essentially, it's for oligo recurrent cancer up to 5. So I think that should be increased to 5, up to 5 metastases, and also include additional synchronous metachronous settings. I also want to comment on prostate cancer, there's much more data to support the use of SBRT, in the oligometastatic setting. We have now 3 prospective randomized trials that support this. The Stomp trial out of Belgium, the Oreal trial out of Johns Hopkins, both, both randomized trials for up to 3 or up to 5 metastases support the addition of or support, adding or treating all of the in the oligometastatic setting, and in addition, this is, in addition of course, to the Saber Comet which included prostate but other histologies. But recently the, the Extend, study, the Extend randomized trial, supported the use of SBRT in addition to hormone therapy in the oligo-progressive setting. so I think that in prostate cancer is really well established, that SBRT is appropriate in up to 5 metastases.

Christopher Loiselle Hi, Chris Loiselle joining Bob Meier. Thanks for the opportunity to give comment. We had submitted a very simple slide as well. I don't know if you bring that up.

Val Hamann (HCA) Yes, I can.

Christopher Loiselle Thank you. I think it's very important work here the assessment of SBRT and I wanted to inquire on the policy considerations of stereotactic radio surgery as well. Could you comment, please, on the scope of the literature assessment, for intracranial SRS? We noticed that a few major diagnoses classes such as trigeminal neuralgia and essential tremor, were not in the evidence report. Can you hear me? Okay.

Sheila Rege Again, just process, can you mention your process?

Christopher Loiselle Sorry Sheila, I see that we can barely hear you.

Janna Friedly Yes, thank you. So before you get you get started, could you please just any disclosures and introduce yourself?

Christopher Loiselle Oh, my mistake, sorry. Yeah. Hi, Dr. Chris Loiselle, I'm a radiation oncology with a radiation oncologist with the Tumor Institute Radiation Oncology group, my disclosures are very similar to that of Bob Meier. We have a joint venture and stereotactic radio surgery and stereotypic body radiation therapy with Providence Swedish and I have at times been a paid speaker on behalf of accurate the maker of CyberKnife and Electa the maker of Gamma Knife and just in, in the big picture Janna we are wondering about trigeminal neuralgia and a central tremor. This was missing in the report, and we generally view the treatment, treatment of medically refractory trigeminal neuralgia, medically refractory essential tremor as standard of care, and we often have to go through a lengthy peer-to-peer review and extra evaluation process for anyone who whose insurance policy is dictated by the Washington Health Care Authority policy document. And I was wondering is that an oversight that was left out or?

Janna Friedly My understanding, and we can clarify this but that is out of the scope of this particular report and coverage decision. So that's that would be a separate, a separate process.

Christopher Loiselle Got it. So the scope of this current policy document is intended as extra cranial, stereotactic radiation treatment only?

Janna Friedly Yeah, so in on the website, there's the report that has the, the scope of the report and, and so you can reference that on the on the website. But it does not include the trigeminal neuralgia and essential tremor.

Christopher Loiselle So it is it possible that's an oversight in that that should be included in this scope of work? Because that is it, those are very strong indications for intracranial, stereotactic radio surgery.

Janna Friedly Yeah, so. And Josh, maybe you can speak to process. But, but for topics that are not, you know, not, within the scope of the topic presented today there is a process for suggesting those as coverage review topics. But, but that was not within the scope of, of today's session.

Josh Morse (HCA) Happy to comment on that, Janna. Here, let me just manage the.

Val Hamann (HCA) And we are at a 2 min warning.

Josh Morse (HCA) These are specifically out of this scope, of um, the topic, if you look as you pointed out, boy, really struggling.

Christopher Loiselle Yeah. Okay. I'll take that clarification move on. Thank you. The other area that we felt as though was lacking in the evidence report was that for cases of reirradiation. Most policies cover SRS and SBRT in the setting of prior radiation treatment, we generally view this as standard of care and in Sophie's discussion we also saw that there was no mention of reirradiation indications. And it, you know we have very limited time here, and we appreciate the again opportunity to comment, but I will say that on a very practical basis, Sophie made the comment that you felt as though

there was clear evidence that SBRT is inferior in terms of outcomes for early stage lung cancer in comparison to surgery and I want you to know that that's not our clinical experience whatsoever, and you know, potentially, if helpful, I would encourage you to perhaps speak to some patients who have undergone both treatments as we have many.

Val Hamann (HCA) Last 30 seconds.

Christopher Loiselle And thank you, and that I think it's very important to sort of couch this evidence in the context of clinical experience, and I look forward to Dr. Lo's comments on that point and others. In the very big picture we do find stereotactic radiation to be incredibly cost effective, really, across indications and I want the panel to understand that this is where the feed of radiation oncology is heading more and more each year. We treat patients with very short courses of image guided high dose radiation treatment to very specific targets.

Val Hamann (HCA) Thank you for your comments. We will have to thank you. We will have to move on.

Christopher Loiselle Thank you.

Val Hamann (HCA) We appreciate you taking the time. Next up we have, we had about, yeah, we had 5 from UW Medicine Radiology group that had reached out for public comments. So again they will be pooling their time, and Dr. Kim did in send in some slides as well, and promoting him to be a panelist, and he should have access.

Edward Kim Well, can you guys hear me? Okay?

Val Hamann (HCA) Yes.

Edward Kim So I actually did prepare some slides. But sorry, first introduction, so my name is Ed Kim, I'm a radiation oncologist at the University of Washington and Fred Hutch, Cancer Center. No financial conflicts or industry, I guess, conflicts of interest. I am a member of the NCCN soft tissue sarcoma panel, and I guess I'm also a State employee, so the topic we're discussing affects my insurance coverage as well. But so I actually had prepared some slides kind of to review some evidence that wasn't maybe included in the evidence report. But and that was really focused on topics of sarcoma and GI malignancies because those diseases that I'm most comfortable with, or that I treat in my everyday practice. Having actually reviewed the, the AMDG recommendations, I guess I would say those recommendations actually address a lot of the concerns I had about access to SBRT for patients with oligometastatic disease. So I don't alright, I guess, since the references that I included are in the record, I don't think I need to walk through them with you. If that's okay, don't anticipate any objections. Um, the, I guess, the only points I wanted to clarify were with these revised recommendations, will these be adding to the, the recommendations from the 2012 report, or replacing them? Just because I noticed that, you know, spine and para-spinal structures or tumors we're included

	the past, but were not commented don't happen in this report, similarly, CNS primary metastatic tumors were not commented on this report.
Janna Friedly	Yeah, so those are, this is a separate and so that this is not to supplant that the decision for those. So those are not part of this process today.
Edward Kim	Okay. And I guess one other comment from one of my colleagues, and I will mention to actually, I believe, my colleague Dr. Apisarnthanarax may also have some comments. I think my comments, I'll be able to wrap mine up fairly quickly. Under lung the proposed policy was to restrict SBRT coverage for t1, t2, and 0, non-small lung cancers. One of my thoracic surgery colleague, or thoracic oncology, patient oncology colleagues noted that NCCN guidelines actually also include SBRT for t1, t2 and 0 small, so on cancers. Oh, we can join as a panelist, and.
Val Hamann (HCA)	And you are muted.
Edward Kim	Sorry about that, I guess, when I switched status I got muted. So yeah, so basically, I guess the question would be, would it make sense to include small cell lung cancers, so the very small subset of t1, t2, and 0 lung cancers small cell lung cancers that are medically inoperable, or patients for whom surgeries otherwise not recommended. That's a very, very small subset of small cell lung cancer patients, the majority present with much more advanced disease. But and NCCN recognizes for that very small subset of patients that SBRT is a reasonable viable treatment approach. Just 2 other quick comments, I guess I would echo Dr. Loiselle that radiation is often considered to be a standard indication for radio surgery, so I guess I echo that comment, and, and it sounds like benign conditions are out of scope, but it's possible that for certain situation, such as AVMs or trigeminal neuralgia radiosurgery is often recognized as a standard care option or treatment modality and it can be kind of confusing, I think with the because this is a health technology kind of application, I guess I just wanna ensure that the omission of those conditions meaning that their not in scope for this analysis doesn't mean that or doesn't get interpreted as those are conditions that are never covered. And I think I'll I can conclude my comments there. Thank you.
Janna Friedly	Great. Thank you very much. And just to clarify this committee today, again, is not covering those benign conditions and are making no coverage decisions on those whatsoever.
Val Hamann (HCA)	And we had another individual from UW, I believe.
Smith “Jim” Apisarnthanarax	Is that me? Am I up? Okay? Hello, everybody. Thank you for allowing, allowing us to give comment. My name is Smith or Jim Apisarnthanarax also radiation oncologist at University of Washington, Fred Hutch Cancer Center. I don't have any financial conflicts of interest to disclose. Perhaps to get some context, just to introduce myself as well, I, I served as the vice chair of the ASTRO task force to come up with a liver guidelines within ASTRO, and I was also the first author of the guidelines. So, just, just to clarify, I saw the recommendations for the AMD regarding HCC for SBRT.

	I just wanted it to be clear that typically for SBRT there's really no size limit that we would apply. Similarly, if you think about it for a surgeon, a surgeon would resect, not limiting to tumor size, but rather how maximally safe a resection can be performed. And so whether it's 6, 6 cm or 7 cm, or 8 cm, it doesn't really matter. It depends on what is achievable safely and so, so I would advocate that size restriction should not be imposed on any of these recommendations. I'll also mention which I included in the abstract recently completed, and about to be published RTOG 1112, which is randomizes a high risk HCC patients to sorafenib plus or minus SBRT. They allowed up to 20 cm in that trial, and just, you know, for those that have read it this trial is a positive trial, it actually improved overall survival, and the actual median size of patients enrolled in that trial was actually about 8 cm. So again, just emphasizing that there should not be a size criteria imposed on, on the recommendation. I'll also speak about the bridge to transplant and indication, as I didn't see that that was included in the AMD recommendation for HCC and then it's true that in our guidelines, and ASTRO guidelines we did look at that. Unfortunately, there's not a lot of data to help guide us, but I think from a practical standpoint, there are patients who are not candidates who are on the transplant list and need bridging. I'll also remind that there is actually no randomized evidence for any bridging therapy, and so we would be lumped in into the efficacy or you know, value of RFA or a catheter based therapies, or for as a bridge to transplant. And so there are patients who need a bridge to transplant to stay on the list of transplant
Val Hamann (HCA)	This is your 2 min work.
Smith "Jim" Apisarnthanarax	that cannot get catheter-based therapies or RFA as a bridge, to transplant, and so removing external beg radiation of any kind, especially SBRT, which would be the safest. One would limit the ability for, for us as physicians to be able to bridge patients to transplant. Lastly, I'll mention about renal cell carcinomas I noticed that was not included, and again, these are the patient populations that unlikely we'll ever have a randomized trial for these patients, for SBRT. The vast majority of these patients are older, medically inoperable, and likely are not candidates for systemic therapy as well. So in those patients to withhold SBRT when they can't get surgery or any other invasive therapies would be, I think, a limitation to our patients that are more frail, and medically inoperable. So I would advocate that at least consideration of medically inoperable renal cell cancers are included. That's all that I have for my comments. Thank you.
Val Hamann (HCA)	Thank you. We did also have a David Kantorowitz on the docket for public comments. However, I am not seeing them in, as an attendee, so if you are here, please either raise your hand or indicate what your name is in the chat. Other than that I'm not sure if there are any other public commenters that are that did not sign up that are wishing to speak today, if you could raise your hand, or indicate in the chat, as I have not seen anybody else. Gary, you have your hand raised.
Gary Franklin (L&I)	It looks like there's a Christopher Loiselle.

Val Hamann (HCA) Yeah. He already went.

Gary Franklin (L&I) Oh, okay. I'm sorry.

Val Hamann (HCA) Last call for any other public commenters that may have not signed up. Okay, I'm not seeing anybody else indicating by raising their hand or putting in the chat that they would like to give public comment today.

Janna Friedly Okay. Great. Thank you very much for those for those comments and I know there were a lot of questions raised, and we will do our best to address those as we discuss the evidence as we go forward today. So thank you very much for all of your insight. So we are going to, we have on our schedule now to take a 10 min break before we start the evidence report. We're running just about 5 min behind, but I think I think taking a 10 min break would be a good thing to do before we start the evidence report. So if we could make sure to come back by 9:55 at the very latest, and we'll get started with that. So if everybody could turn their video on when they were back on, that would be helpful. So we can make sure that we have everybody before we get started again. Great. Thank you. So I see. And we have all of the committee members back on. So I think it's 9:55 So I think that we should go ahead and get started. So we are going to spend the next hour or so on the evidence report, and then following that we'll have an opportunity for about 30 min of question and answers for amongst the committee and, and discussion so why don't we turn it over to Val and Beth.

Beth Shaw (CEbP) Thank you. I'm hoping you can hear me all right. Yeah. And you can see the slides as you expect them.

Janna Friedly Yep.

Beth Shaw (CEbP) Fantastic. Thank you so much. So. Yes, thank you. I will be presenting our evidence report on stereotactic radio surgery and stereotypic body radiation therapy. This is the final evidence report and whilst I am presenting it, you will soon realize that this certainly was a team effort. So we've heard a bit about the technology already. So I'm not going to go through this in any great detail. But you can see here what radiation therapy is, and those different common types of radiation therapy, including stereotactic body radiation therapy or SBRT. As Sophie already mentioned this is a type of radiation that's typically delivered in far fewer fractions and can be a primary treatment for early stage cancers, discrete tumors, and oligometastatic disease and you know, for these other selective begin neoplasms in or near the central nervous system, or in those in the current cancer within previously irradiated regions. Again, there are, with a radiation-based options, some of which Sophie touched on earlier. So just to give you an idea of some of the clinical need in 2019, nearly 2 million cases of newly invasive cancer was reported in the US and whilst cancer does affect people of all ages, races, ethnicity, and sex, it does not all affect all groups equally. So things, like genetics, lifestyle, environmental exposures, and other factors can lead to differences in risk and for most cancers, age is the most important risk factor with around 58% of cancers occurring in adults aged 65

years and older. Tt's worth noting that SBRT may not be appropriate in many cancers. For example, if we think about the group of lymphomas, SBRT is just not really an option, because the area needed to treat is too diffuse for this type of radiation. So again, we've talked a lot about the history of this topic within Washington's HTA program so this is just a reminder of those coverage determinations, and you know the specifics of those just to state again in this evidence review we explicitly excluded any covered conditions, hence the reason that we've not looked at stereotactic radio surgery nor have we looked for SBRT for those covered conditions, so cancers of the spine, paraspinal structures, all that inoperable non-small cell lung cancer stage one group. So in 2012, sorry since 2012 we've conducted 3 signal search reports, 2 of which were published and based on newly available evidence, SBRT was selected for rereview with the aim of conducting updated evidence searches and producing an updated evidence review for you as the committee to consider for an updated is coverage, coverage decision. I've got a few abbreviations here many of them will be very familiar to you, but there's a lot of them. So just please refer back to these ff there's anything that you need to. Again Sophie's mentioned this, we have our key questions. We are looking for the effectiveness in cancer is not currently covered. We're looking at them for harms, and campuses that are not currently covered and specifically for any differential efficacy or harms, maybe by patient characteristic cancer type, site or GRADE setting or provider characteristic as well as costs and cost-effectiveness. So the methods for this these are reported in much greater detail, detail in the report, so please do refer to that for any specifics but what we did is we went back to that previous report, and the signal searches, and we rescreen studies identified in those reports against the criteria that we used for this update. We checked all the studies submitted during the public comment period on the PICOTS and key questions. We ran database searches in Ovid, Medline and Cochrane libraries. We search websites and databases for clinic, for clinical guidelines. We searched FDA databases and clinical trials.gov for harms and ongoing studies and do we assessed the risk of bias in each of the included studies, using standardized checklists and then we assessed the certainty of evidence for key outcomes using the GRADE approach. So, just as a reminder when we talk about risk of bias assessment studies at low risk of bias have clear reporting of methods and then mitigate some of the potential biases within the study. Whereas, if we were to study as being high risk of bias, we have assessed that study as having clear flaws that might introduce serious bias, particularly to the results of that study. And for GRADE, the certainty of evidence we graded overall survival, we graded progression, disease, control, quality of life and toxicity as well as cost and cost effectiveness. So again, if we have high certainty of evidence, we're very confident on that finding, and in essence we may mean that, you know future is, a research is unwisely to change our understanding. However, if we're in the low to very low certainty of evidence, we have low to no confidence in what we've learned about that effect of the intervention on the outcome and future research is therefore very likely to change our understanding of the effect of that intervention. It's just worthwhile noting here that we only GRADE the outcomes from

randomized, controlled trials and comparative studies. Whilst we do report outcomes from non-comparative studies in the report, we did not GRADE them so we're not presenting that data. In your presentation, but all the data on harms from those non-comparative studies, again, is in the report. Just a quick reminder of the outcomes. So we're talking about things like overall survival, which is easily and precisely measured, generally based on objective quantitative assessment. However, some of the disadvantages are that it may be affected by switch over of controlled treatments, it generally needs longer follow-up in the studies, and it can include non-cancer deaths. So often studies report disease. Free survival or event, free survival, and the advantage of this is, it can be generally assessed earlier and with smaller sample sizes than overall survival studies. But again, there's some disadvantages to that, including being potentially subject to assessment bias, particularly in open label studies. We also report from progression-free survival, which again has similar advantages to disease-free or event-free survival. However, again potentially subject to assessment bias, and most importantly, may not always correlate with survival. Then we have measures of disease control, such as objective, complete response rate. The effect of this, to the effect of these can be attributed to the drugs or other treatment, not natural history, however some of the downsides are that the definitions can vary amongst studies. You need frequent radiological or other assessments to assess this type of outcome, unless with progression-free survival these disease control may not always correlate with overall survival. So moving into the findings of the updated evidence review. Here's the standard prism diagram. So you can see at the top left hand box we searched nearly 4, well, we identified nearly 4,000 records through our database searching in a further 148 through other sources. After duplicates, we had around 2,000-2,500 that we screened, and we were able to exclude the vast majority of those. But then we assessed 644 at full text and overall in this review, because of the number of cancer sites, we included 133 studies reported in a 158 publications. So I'll now take you through the findings. You can see here the list of cancer sites we took, we prioritized these by prevalence within the State of Washington. So breast, prostate, and lung are the most prevalent in Washington. Moving down the list, you can see the cancer sites in bold in indicates cancer sites of which we did not identify any eligible studies through this update. So none of the studies met our inclusion criteria for breast, colorectal, colorectal, uterine, rhein, ovarian, cervical, esophageal cancers, we didn't identify any eligible studies. So I'm going to go through each of the other sets of cancer sites again in this order, and we're going to start with our findings around effectiveness. So for each of these sites I will talk about, I'll give you the information that was provided in the 2012 report, and then an overview of what's included in the update. I'll talk you through some of the details of the randomized control trials. But not the non-randomized studies, simply just because of the volume of the evidence in this review. We'll go through the GRADE tables and again, I'll only summarize those because of the time. But the information is there, so we can go back to them as needed. Then I'll talk to you through a summary evidence statement, and then the information from the guidelines. Once we finish this

evidence section, we'll then move into some information on toxicities, and then we'll talk about cost-effectiveness. So let's start with prostate cancer. So in the 2012 report the overall strength of evidence was assessed as being very low for harms based on 4 case study. There were no comparative studies on the effectiveness of SBRT in this particular cancer site. In 2023 we were able to identify 4 randomized controlled trials, 14 comparative, non-randomized studies, and 18 non comparative studies that we used for harms only. So here are the 2 rounds controlled, 2 of the however, many did I say 4 ,2 of the 4 randomized, controlled trials. So we have the PACE-B trial. So this was published in 2019. They included 874 men with low to intermediate risk, localized prostate cancer, and had compared SBRT with conventional radiation therapy or moderately high perfectionated radiotherapy. This study is the CyberKnife platform was initially mandatory for all stereotactic body radiation therapy, however sponsorship changes prompted a protocol amendment permitting delivery on conventional linear accelerators. Then we have the ASSERT trial, smaller trial here that included 80 men with intermediate to high risk localized prostate cancer. Then this compared SBRT with moderate hyper fractionation randomized control trials. Both of these studies were assessed at moderate risk of bias, and there was no information from the ASSERT trial in 2022 on the type of equipment used in this trial. Moving on to the next 2 trials, we have the Lukka trial, published in 2018, which included 255 men with localized t1 to t2 stage, stage cancer and compared to SBRT with upper ultra hyper fractionated radiotherapy. In that particular trial the centers could use CyberKnife or IMRT or vMAP techniques or protons. And then in 2019, Widmark et all publish the HYPO-RT-PC trial. This included 1,200 men with intermediate to high risk localized prostate cancer, and compared SBRT with conventional radiation therapy. There was no information on the equipment used in that particular study. In the non-randomized studies that were identified the majority of the studies either said that they used the CyberKnife system or no information was provided. So, moving now into the GRADE tables, like I said, I'm not going to go through these in any great detail, but you can see here that we have evidence comparing the SBRT versus conventional radiation therapy from that single randomized control trial. The evidence varies here from very low for disease control up to moderate evidence around progression-free survival, quality of life was not reported in that randomized control trial. When we look at SBRT versus other forms of radiation therapy for localized prostate cancer, we have low certainty of evidence around both overall survival and disease control based on 4 or 5 non-randomized studies, but they were comparative studies. Progression-free survival was not reported in any of these studies. And then we have 3 randomized, controlled trials that reported on quality of life, looking at SBRT versus other forms of radiation therapy for all risk groups of localized prostate cancer low certainty of evidence for this. So based on the studies it included in this review we concluded that SBRT may be similarly or more effective than other options for individualized with localized prostate cancer. However, the certainty around that evidence range from very low to moderate, and was based on 4 randomized controlled trials, and those 14 comparative, non-randomized studies.

We of the guidelines that we identified we assessed these being from good to poor methodological quality, but eligible guidelines did make primarily conditional recommendations on the use of SBRT as an option for treating prostate cancer. So you can see strong recommendations from ASTRO and the American Neurological Association on the use of SBRT for low or intermediate risk localized prostate cancer. The wording suggests a conditional approach with SBRT being offered as an option. The 2022 European joint guidelines recommended SBRT solely as the subject for future investigation and not for routine treatment. And then the FROGG guidelines from 2018 recommended SBRT as an option for metastatic disease or a salvage therapy. However, they noted that there was that the evidence was inconsistent and was of low quality and they're specifically highlighted the need for more clinical trials. Moving now into our lung cancer topic. Again, you can see that in 2013 the following coverage determination was adopted around the use of SBRT for an inoperable non-small cell lung cancer stage one, and that 2012 report included 20 non, non-competitive, non-randomized studies in lung cancer. But that was across all types of lung cancer, not just in that specific population currently covered. In the 2012 report, they noted that populations in the studies tended to be mixed and included both primary lung cancer and metastatic lung cancer, and there was no coverage determination for those other forms of lung cancer other than that stated above. We've moved on a bit in the 2023 update. We have now included 2 randomized control trials, 11 comparative non-randomized studies, and 11 non-comparative studies that were used for harms. So talking about the 2 randomized controlled trials that we identified for this lung cancer, we have the first one published in 2021 by Altorki et al. This included 60 people with potentially resectable early stage non-small cell lung cancer, these were stages 1A to 3A and they compared the use of SBRT plus or minus durvalumab. We then have the PEMBRO-RT trial that was published by in 2019. This included 78 people with advanced non-small, so non-small cell lung cancer and compared again the use of SBRT plus or minus the use of pembrolizumab. Neither of these studies reported any information on the machine used. In the non-randomized studies for this particular cancer there was mostly no information, but some studies reported these CyberKnife, and some were reported the use of the LINAC accelerator machines, such as Electra, Synergy, or Clinac. Again, I won't go through this in detail, but you can see here we've got certainty of evidence that ranges from very low to moderate certainty of evidence. When we were looking at SBRT versus surgery or no SBRT for operable early-stage non-small cell lung cancer. So we have information here on overall survival progression-free survival and disease control, but no information on quality of life. hen we look at SBRT versus radiation therapy we're in operable stage to lung cancer, we identified one comparative, non-randomized study that reported on overall survival. Uncertainty of evidence from that study was assessed as being low certainty of evidence. And then we have that single, randomized, controlled trial that was looking at SBRT versus no SBRT for advanced non-small, small cell lung cancer. Again, it reported only on overall survival and progression-free survival, and those recessed respectively, as being moderate and low certainty of evidence.

When we look at SBRT versus surgery or conventional radiation therapy for lung metastases, we have a number of comparative non-randomized studies that reported on overall survival, progression-free survival, disease control. However, because of the nature of the study designs they were assessed as being of low and very low certainty of evidence. When looking at LCNEC of the lung, we have SBRT versus surgery, or conventional radiation therapy. This was reported in 2 non-randomized studies that looked to overall survival alone, and that was assessed as being a low certainty of evidence. So based on the studies included in this review, we concluded the SBRT may be similarly or more effective than radiation therapy for an operable stage 2 non-small cell lung cancer, low certainty of evidence, or when used in combination with pembrolizumab compared with pembrolizumab, pembrolizumab alone for advanced non-small cell lung cancer, again low to moderate certainty of evidence based on that single randomized, controlled trial. SBRT also appears to be similarly or more effective than conventional radiation therapy for people with lung metastases, again, very low to low certainty evidence based on those comparative non-randomized studies. Well for large stage or endocrine, carcinoma, LCNEC of the lung, and again low, certainty of evidence based on those 2 comparative, non-randomized studies. However, it may be less effective than surgery for lung cancer that is resectable and that's very low to low certainty evidence based on 10 comparative non-randomized studies. And based on guidelines, and these were assessed as being a good to moderate quality. Guidelines, the guidelines indicate that there is some evidence for these, for SBRT in certain types of lung cancer, the evidence quality sighted was generally moderate to low quality and in the guidelines they usually recommended SBRT for patients who refused or were at high risk for surgery, lobectomy, or chemotherapy. For patients who are operating. SBRT is still considered a therapy under investigation, under investigation in the current guidelines that we looked at for this report. Moving now to melanoma, in 2012 the overall strength of evidence was assessed as very low for harms based on 7 case series and no comparative studies were identified. For this 2023 update, we identified a single randomized control trial in a specific type of skin cancer, which is Merkle cell carcinoma. The single trial was published in 2022, and included 50 people with advanced Merkel cell carcinoma, and they compared the use of SBRT with the use of drugs, so nivolumab and ipilimumab. So from that randomized control trial, you can see the use of SBRT with those drug regimens versus the drugs alone for that Merkel cell carcinoma

based on that single randomized control trial we have low certainty of evidence across the board here for survival, progression-free survival, and disease control. They also reported on the toxicity which should actually be in the in the next set, so ignore that one. So based on the studies included in this review, we concluded that SBRT in combination with these 2 drugs, may be as effective as the drug regimens alone for Merkel cell carcinoma so it doesn't really add too much to the use of those 2 drugs alone. Melanoma, the single eligible guideline of moderate quality, recommends the use of SBRT for local regional recurrence of melanoma, generally, or single distant metastases. However, the evidence again, for that

recommendation was based on low quality evidence. Moving into renal cell carcinoma. There were no eligible studies identified in the 2012 report, and in the 2023 update we found 2, 2 non-randomized studies. One is a comparative non-randomized study and one is a non-comparative study for harms only. There was no information on the machine used in any of those, well, neither of those studies. So, looking at the single comparative non-randomized study, where they compared the use of SBRT with conventional radiation therapy in stage one renal cell carcinoma, you can see, we only have low certainty of evidence on overall survival. So based on the study, study included in this review, we conclude that SBRT may be less effective than ablation, and there's a range of ablation studied in that study. Maybe less effective than ablation of surgery for stage, one renal cell carcinoma, and that was low certainty evidence based on that single comparative, non-randomized study. And overall the guidelines that we looked at were moderate to good quality and they make conditional recommendations on the use of the SBRT in certain clinical situations, and particularly they called out the use of SBRT for metastatic disease, or when patients are considered unsuitable for the surgery. However, that's based on low to moderate quality of evidence. Again, in this case, the guidelines also highlighted the need for future clinical trials on the use SBRT in renal cell cancer. Our next cancer site is the pancreas, and in 2012 the overall strength of evidence was assessed as very low for effectiveness and harms based on one systematic review and 4 case series. In the 2023 update we were able to identify 3 comparative, non-randomized studies and of these only one study reported using a specific machine where they used a LINAC radio surgery or Gamma Knife. So looking at this comparative non-randomized study, we have one here that looked at the effect of SBRT versus chemotherapy, or IMRT for unresected pancreatic cancer. We have low certainty, but evidence on the overall survival there. And then in the second study, where we are looking at SBRT versus conventional radiation therapy for locally advanced pancreatic cancer again, low certainty of evidence from this single comparative, non-randomized study. So based on those 2 studies, we concluded the SBRT may be more effective than chemotherapy, or IMRT for unresectable pancreatic cancer and it may be more effective than conventional radiation therapy for pancreatic cancer. Both of those are low certainty evidence. In 2019, Astro made conditional recommendations on the use of SBRT for treating pancreatic cancer. However, that again, was very low to low quality of evidence, and they recommended that following surgical resection, SBRT should only be used in the context of research. Moving now into head and neck. Again in 2012 the strength of evidence was assessed as being very low, and no comparative effectiveness studies right. In the 2023 update we have a single randomized control trial and 4 comparative non-randomized study. So this is the study that was published in 2021 by McBride and colleagues. It looked at 62 people with metastatic or recurrent head and neck squamous cell carcinoma, and compared SBRT with nivolumab. There was no information in the machine used in this randomized, controlled trial. However, where reported in the non-randomized studies, CyberKnife was the machine that was used. So looking at data here from one of the non-randomized studies, this

compared SBRT versus brachytherapy for early stage or oropharyngeal cancer. This certainty of evidence across each of these outcomes, which included quality of life was low certainty for evidence. Looking at the randomized controlled trial as well as the non-randomized by studies, this was comparing the use of SBRT versus other treatment options for recurrent or metastatic head and neck cancer. We have moderate quality of evidence around overall survival from the randomized control trial and low certainty of evidence from those non-comparative, sorry from the comparative non-randomized studies. Looking at again that, those randomized, that randomized control trial and the comparative, non-randomized studies, you can see again moderate certainty of evidence around progression-free survival, low certainty of evidence for disease control. So based on those studies included in this review, we conclude the SBRT may similarly effect to brachytherapy, when used as a boost treatment after conventional radiation therapy for early stage or oropharyngeal cancer, however, that was low certainty of evidence. However, SBRT may be less effective than charge particle radiation therapy for recurrent or metastatic head and neck cancer. But similar similarly effective to IMRT and conformal radiation therapy. But the certainty of evidence range from low to moderate, depending on the source of the evidence for that. We did not identify any eligible guidelines for this particular set of cancers. So moving now into liver cancer. Again in 2012, there's very low certainty of evidence based on 2 systematic reviews, but of case series and 7 case series. Now in 2023, we've included 20 comparative, non-randomized studies and 11 non-comparative studies. Most studies did not report specific equipment used, but some have CyberKnife some reported these LINAC accelerated machines. So, looking at the information where we've got studies, comparing SBRT versus RFA for early stage hepatocellular carcinoma, the evidence ranges from low to very low. Looking overall survival, progression-free survival and disease control, but no information on quality of life. When we're looking at SBRT versus RFA on small liver cancers, you can see again, very low to low certainty of evidence around overall survival and progression-free survival. The information again from those 4 comparative non-randomized studies, again, is very low around disease control. And when we're looking at SBRT versus other treatments on resectable HCC you can see low quality of evidence for overall survival and progression-free survival as well as the disease control. When we're looking at SBRT versus sorafenib for advanced hepatocellular carcinoma, you can see we have a single comparative non-randomized study, and the evidence around survival and progression-free survival was respectively low and very low. We have some information on one of the populations that was talked about earlier. So this was SBRT versus other treatment as bridging therapy for people on a waiting list for liver transplantation due to liver cancer. So we have 2 non-randomized studies here again, the evidence around survival and disease control ranges from low to low. And then we have this single non-randomized study that looks at SBRT versus TARE or conventional radiation therapy for unresectable intrahepatic cholangiocarcinoma and that was low certainty of evidence around overall survival. So in summary he can see that, based on this evidence, we concluded the SBRT may be as effective as

radio, radio frequency ablation for early stage of the cancer. However, results were mixed, and that was a very low to low, sensitive evidence. SBRT either used alone or in combination with TACE, maybe as effective as RFA or TACE alone for those small liver cancers, very low to low, sensitive evidence, and for unresectable liver cancer, low, sensitive evidence and SBRT may be more effective than sorafenib for advanced liver cancer. Again depending on the outcome, very low to low certainty of evidence. We also noted the SBRT may be similarly or more effective than other options when used as bridging therapy for people on the waiting list for liver transplantation. And that's very low to low, sensitive evidence it may be more effective than sorafenib for advanced liver cancer again, very low to low certainty of evidence, and may be more effective than TARE for unresectable ICC low sensitive evidence based on a single non-randomized state. From the guidelines that were good to moderate quality, you can see here that for biliary tract cancer, SBRT was conditionally recommended in some specific condition of situations based on low to moderate evidence quality. For liver cancer SBRT was recommended as an alternative for treatment of local failure, for certain tumors based on again low to moderate certainty evidence. And in 2022, with the American College of Radiology, appropriateness criteria so I think that SBRT may be appropriate for a range of specific layers cancer types. However, the strength of evidence was not reported for those appropriateness criteria. Moving now until oligometastatic cancer, then in 2012 2 non-comparative studies, and as we know, no specific coverage, determinations were made. In 2023, we now have 3 randomized control trials, 3 comparative non-randomized studies and those 12 non-comparative studies. So these are some of the trials that were mentioned earlier. So we have to STOMP trial, published in 2017 that looked at 62 men with recurrent oligometastatic prostate cancer, and this, compared to the use of SBRT versus surveillance. We have the SABR-COMET trial published by Palmer et al published in 2019 that randomized 99 people with a controlled primary tumor on 1 to 5 oligometastatic lesions and they were randomized to SBRT or to standard of care. And in the ORIOLE study you can see here they had 54 men with oligometastatic prostate cancer, and they were randomized to SBRT and observation. None of the randomized control trials reported using any specific machines and in the non-randomized studies most of them, again, did not report on the specific equipment used but things like Cyberknife, RapidArc on Truebeam, and non-robotic LINAC accelerators when mentioned. So the findings from the RCTs and the non-randomized studies for oligometastatic cancer, you can see here that when SBRT is compared with standard of care for a range of oligometastatic cancers, and the primaries were mostly adrenal, bone, liver, and lung. You can see here the evidence across these outcomes in quality of life ranges from low to moderate certainty of evidence. And specifically, when we're looking at SBRT versus observation for oligometastatic prostate cancer, we have those 2 randomized trials again reporting across the outcomes, including quality of life and certainty of evidence across these was assessed as being of low. And then we have the final comparison here which is looking at SBRT versus radiation, therapy or no SBRT for oligometastatic prostate cancer. Again, survival

and disease control and the certainty of evidence range from low to very low. So based on the studies included in this review, we concluded the SBRT appears to be more effective than standard of care or observation for oligometastatic cancer, low to moderate certainty that evidence based on those 3 randomized, controlled trials and for the oligometastatic prostate cancer, however, elected nod of radiation therapy may be more effective than SBRT and that's very low to low certainty evidence based on the 3 comparative, non-randomized study. We did not identify any eligible guidelines identified for this group of cancers. However, it is worth noting that there may be other site-specific cancer guidelines that use, that talk about the use of SBRT for a specific oligometastatic disease state associated with those specific primaries but we didn't identify any guideline that really focused on oligometastatic cancer alone. Looking now quickly at adrenal cancer. The in 2012, very low certainty of evidence, based on 2 case series not really moved much in the evidence space for this particular cancer. We were only able to identify a single non-comparative study that we used for harms only, and we did not identify any eligible guidelines. For bone cancer, there were no included studies other than those for spine cancers which are a covered indication. So we did not look for these in the 2023 review. But we did identify one newly, well, one randomized control trial that have been published since the 2012 report. So this is the trial published in 2019, where they randomized a 160 people with radio logically confirmed painful bone metastasis. They randomized people to SBRT or to standard multi-fraction, radiation therapy, and followed people for up to 24 months. There was no information on the machine used in this trial. And when we look at the comparison of SBRT versus conventional radiation therapy for bone metastases, you can see that from that single randomized controlled trial it reported on survival, disease control and quality of life and the certainty of evidence range from very low to moderate depending on the specific outcome. So based on the studies included we concluded the SBRT may be as effective as multi fraction radiation therapy for painful bone metastases and from the guidelines that recessed as being with moderate to poor quality, the guidelines recommended that SBRT could be considered as an option, particularly for localized or metastatic non-spine, bone cancer. However, the evidence quality, when provided at, tended to be low. One of the questions if you remember, was about the differential efficacy of SBRT. However, few studies, reported on clinical subgroups of interest, but the was some indication that specific populations, and obviously these, would vary by cancer site, maybe more likely to benefit from SBRT compared with other populations. However, one of the challenges as mentioned was the subgroups tended to vary by cath sites and treatment site and what often only reported in single studies. So it was really difficult actually to make any, any robust judgment on which groups of patients, or which specific types of cancers or clinical circumstances would indicate that somebody would be more likely to benefit from SBRT compared with another subgroup. I also just wanted to identify some of the guidelines for which we did not identify any primary studies but where there are recommendations from guidelines on the use of SBRT. So as noted, we didn't find any studies that met our criteria for colorectal cancer. However in general

guidelines that were assessed as being of good to moderate quality, do recommend SBRT as an option for metastases of colorectal cancer, particularly in people who are not considered good candidates to surgery. We also had a series of gynecological cancers where we didn't identify any studies that would meet our inclusion criteria. But we do have a couple of guidelines that were assessed as being of good quality, but make conditional recommendations for the use of SBRT for patients with cervical or endometrial cancer. And again, these were specifically for people with metastases or those who are high surgical risk. However, again the evidence quality, when provided, was low and actually just to note in May of this year, those European guidelines and cervical cancer were updated, and they have a single recommendation says the management of oligo organ metastases should be discussed in a multidisciplinary, setting, etc. but one of the treatment options alongside local reception thermal ablation, interventional, brachytherapy, or would be the SBRT would be one of those options, however, based on local quality evidence, and they believe that the, the evidence, showed limited clinical benefit. However, they did make a positive recommendation just earlier in this month. We also found a single guideline on testicular cancer that was of moderate quality, and they consider that SBRT could be an option for salvage treatment in this particular cancer and they did not give any information on the strength of recommendations. So we're now moving to an overview of the toxicity that that we found on in the, the information on toxicities that we found in the evidence. I will do this only at a high level, and you can see a lot more information in the report. For example, on things like timing of toxicities, you know whether these were acute toxicity, or whether it was a light toxicity experienced in the patient journey. So I'm gonna run through these really quickly, but you can see here are the toxicities from randomized control trials and comparative non-randomized studies for prostate cancer and that ranges from low to moderate certainty of evidence. We have the information on lung cancer again low to moderate certainty of evidence. We have some information from that single randomized, controlled trial, so low certainty of evidence around toxicities for that advanced Merkel cell carcinoma. Only one non-comparative non-randomized study for renal cell carcinoma. And this was assessed as being very low certainty evidence. In pancreatic cancer from a single non-randomized study. And then for head and neck counts, we have 5 studies, but the certainty of evidence here ranges from low to moderate, depending on that study design. And then for liver cancer, so we have 16 comparative, non-randomized studies, where we assess the evidence as being of a low for this particular outcome. For oligometastatic, we have low to very low certainty evidence. And for bone cancer, we have low certainty of evidence. And I just wanted to site here we've got a couple of other buckets of cancer where we didn't identify any comparative, non-randomized studies, so for things like large tumors and for mixed tumors, you can see that we only identified non-comparative studies. So I didn't refer to them in the effectiveness part of this presentation, but we do include them in the report, for harms only. So overall, based on that series of evidence presentations by cancer site on toxicity, we've concluded the overall SBRT does not appear to be associated with

significantly higher rates of toxicity than other treatment options. As you would anticipate, the types of toxicity varied by treatment site, however, in general events, graded as 4 or 5 level toxicities were rare. As mentioned, there was no comparative toxicity data for adrenal or renal cancers for those large tumors of mixed tumors and for harms. We also look at some of the FDA's databases. So very few reports in the FDA's medical device recall database were classified as being class one, and these are defined as a situation where there's a reasonable chance that a product or intervention will cause very serious health problems or death. So this is really looking at the use of that equipment, which is what we've heard is a really important element in the delivery of SBRT and most of those reports in the medical device recall database were related to software and placement issues. And when we looked at the FDA's MAUDE database we saw similar safety issues reported in that data repository. Again, as with effectiveness, few studies reported on clinical subgroups of interest, but there was some indication, specific populations that, again, may be more at risk of SBRT related toxicity compared with other populations, but as with effectiveness it varied by cancer type and treatment site and were often only reported in single studies, really limiting our ability to make robust judgments on the you know the, the reproducibility of those effects. And again, just to round out the clinical practice guidelines overall, just to say that recommendations on the use of SBRT, both in the guidelines and the payer policies they tended to vary in their approach to the use of the SBRT with some being more supportive of the use of SBRT depending on the cancer site. However, it is worth noting that both the guidelines and payer policies often noted a limited evidence base, but they did sometimes highlight the SBRT may be an option that's preferred by patients because of the fewer treatment fractions and the favorable safe, safety, profile when compared with other treatment options. So let's move now finally into key question 4, which is around costs and cost effectiveness. So we have 2 studies here on prostate cancer. So the first study here is the Pan study by 2018, published in 2018, that looked at men with localized prostate cancer and compared to SBRT with that intensity modulated radiation therapy and this is a non-randomized study that's also included in our kind of effectiveness and harms part, but they also reported on a cost comparison as an outcome within, that, within, that randomized, non-randomized study. Apologies. And then for Parikh et al in 2020 they actually published a cost-effectiveness analysis. So this was looking at the use of men with oligorecurrent hormone-sensitive prostate cancer. And they were looking at SBRT when compared the use, when compared with the use of abiraterone acetate or prednisone or docetaxel both with androgen deprivation therapy. They conducted a cost-effectiveness analysis, using a Markov State transition model and this the analysis was done from a US payer perspective. They took the costs from Medicare data, and they took a 10-year horizon. They mainly based their information on the randomized control trial STOMP that we've just talked about, which is an included study in this review. But they also took information from the stampede trial and the Tax 327 trial, where they took the information there for, and then, from a bit Abiraterone, they used information from the trial designated with the number

CAUAA301. No patient incurred costs were included in either of these 2 studies. So here's the detailed outcomes, both on cost-effectiveness and costs. The certainty of evidence ranged from low to very low. Moving on to lung cancer. I'll bring all the cost effectiveness together at the end. So for lung cancer, we have this again cost effectiveness analysis using a Markov State transition model, and there's they looked at the use of SBRT plus maintenance therapy versus maintenance therapy alone. And this was specifically in people with oligomatic, oligometastatic stage 4 non-small cell lung cancer and they were grouped by mutation status. The group analyze 3 hypothetical cohorts here. So it was the epidermal growth factor receptor group, and they were treated with osimertinib. There was postic-lyphoma mutation positive group, and they were treated with that alectinib. There was a program death ligand PDL1 expressing group who were treated with pembrolizumab and then there was an EGFR and ALK muttered, mutation negative, and PDL1 negative so mutation negative group and they will trade, treated with platinum doublet and I've just added that information here because somebody asked earlier about what the maintenance therapy was used. So you can see here apologies that might be a little bit blurry, but I took a quick screen grab of how these patients progressed through that cost-effectiveness model. Again this was a US payer perspective. They took the costs from Medicare effectiveness analysis, they took a lifetime horizon approach. They use data from SABER COMET which is an included randomized control trial in our review, but they also took data from 2 smaller studies, non-randomized, that would not have met our inclusion criteria. Again, because of the perspective taken in this cost-effecting this analysis there were no patient incurred costs. So moderate certainty of evidence around the cost efectiveness results here from lung cancer. Looking at pancreatic cancer. Again, this is a study that we included for effectiveness and harms that just happened to report on costs. So this was a study in people with non-metastatic unresectable pancreatic cancer. You can see the intervention and the comparators there, and whilst they did report on healthcare payments, they did not look at any patient incurred costs, and we assessed the information on those costs as being a very low certainty of evidence. In head and neck cancers we have again a single cost effect, effectiveness in our in people with unresectable locally recurrent previously irradiated head and neck cancers, and they were looking at SBRT with or without cetuximab and comparing that with platinum-based chemotherapy alone, chemotherapy, plus cetuximab or IMRT plus chemotherapy. Again this took the perspective of the US payer costs from Medicare, and they took a 3 year horizon for this particular analysis. They use data from 8 studies of SBRT, one of which we've included in this report but the other 7 studies would not have met our inclusion criteria. Again, because of the perspective taken, no patient incurred costs were included. We assess this being a moderate certainty of evidence for the cost, effectiveness, cost-effectiveness, outcome. And for people with liver cancer again, cost, effectiveness, analysis looking at SBRT versus radio frequency ablation in people with early stage liver cancer. This analysis again, was from the US payer perspective using costs from Medicare they didn't state a horizon, because this was actually cost-effectiveness analysis that was

conducted alongside a non-randomized study that again is included as the effectiveness. So the medium follow-up this group of patients was 487 days. It was a non-randomized, yes, I've just said that again. No patient incurred costs were included in this particular analysis. We assess this being a moderate certainty of evidence. Looking, at all the oligometestatic cancers. We have 2 cost effectiveness analyses here. Both comparing SBRT with standard care. So both of these studies take a US payer perspective. However, the study by Kumar et al also includes some societal perspective. So they've actually included costs around caregiver costs patient time or salary loss. They've also included costs associated with parking, meals and travel as well as costs associated with productivity loss. In the Kumar study they looked at costs from Medicare and in Mehren's they looked at cost from older studies. The horizons in each of these respectively was 10 years and 16 years. Both of the studies use data from the SABER Comet trial for as primary sources, and both of them then use the SCARE database for those longer term outcomes. What these 2 studies found was that Sabre from Kumar et al was cost-effectiveness, was cost-effective until it started to cost around a 145 to 160, $146,000 and the Mehrens analysis showed that Sabre was cost effective until just under $94,000. And we assessed that information as being a moderate certainty of evidence. We have one cost comparative study here. Again, this is included in the effectiveness and harm section as well. So this was in that group of people with bone metastases, and they took their cost from a Medicare claims database, and they simply looked at the difference between the intervention SBRT and the comparators, and they looked at provider and technical feature. And we assess that, as being a very low certainty of evidence. And so while the economic literature appears to be sparse to be possibly cost effective for oligometastatic hormone-resistant prostate cancer, low certainty of evidence. It appears to be lower in costs, so this is costs, not cost effectiveness than IMRT for prostate cancer, very low certainty of evidence. It appears to be cost ineffective when compared with maintenance therapy. So remember all those different therapies depending on the genetic mutation for oligometastatic lung cancer, moderate certainty of evidence and appears to be higher in costs than conventional radiation therapy or chemotherapy for pancreatic cancer, very low certainty of evidence. And continuing costing effective as irradiation when compared with other salvaged therapies for head and neck cancers, moderate certainty of evidence costs ineffective when compared with RFA. For liver cancer, low certainty of evidence cost effective when compared with standard of care for oligometastatic cancer, so moderate certainty of evidence, and maybe more expensive than other forms of radiation therapy for bone cancer with low certainty evidence. And we were not able to identify any eligible economic in that adrenal or renal cancers. So in conclusion, with some cancer sites, the evidence shows the SBRT has the potential to be an effective option when compared with other existing treatment options. However, this varies by the specific type of cancer in comparative care. However SBRT, for some other cancers remains unsupported with either limited or no comparative evidence of effectiveness. Some guidelines are more supportive of the use of the SBRT but most note that there is a limited

	evidence base, however highlighting it may be preferred by patients because of the fewer treatment fractions and the favorable safety profit of the SBRT when compared with other treatment options. Thank you
Janna Friedly	Great. Thank you so much for that presentation. Very thorough presentation. Unless there are other process issues, we are now open for discussion, questions and discussions from the committee.
Simon Lo	So am I allowed to make comments, or is confined to the committee?
Janna Friedly	No, I think it would, from my perspective, it would be helpful to have your perspective at this point, and the, you know you are a guest committee member for the purposes of this this meeting today without vote, without voting
Simon Lo	Okay. Yeah. So first, and I have to comment about, you know, some of the areas. And I think a lot of the key studies actually have been ommitted, so say, for instance, you know, for lung cancer, there a very important randomized clinical trial actually, it's from STOMP, which is one of the largest trial groups from Australia. STROMP, I think, across many radiation oncology group. So they actually compare three dimensional radiation therapy, which is conventional radiation with stereotypic body radiation therapy. And actually, it's a positive trial showing that SBRT is a superior in terms of a tumor control. And actually that has not been included. It is really key study actually included in my comments for a peer review there.
Janna Friedly	Beth, are you able to to comment on that? And can you? Can you remind me what the name of that trial is?
Simon Lo	Let me see, it's called Chisel, C. H. I S E. L. Lemme see, I actually put it in my review. Let me take a look.
Beth Shaw (CEbP)	I can do a quick response. I can't respond to the specific trial. But I did go through all of your studies, Simon, you know that that was that was really helpful to have those lists. So I went through all the suggested studies, and I will have information somewhere about why it was not included. So I'll try and dig that out. But we did go through all the suggested studies. So we it's worth noting here that just because it's the size of the evidence base and the inclusion of non-randomized studies, this was, we've used a lot of different techniques to try and identify the studies. We did a lot of database searching. We did a lot of manual searching because of the size of this. This so I just like to say, there may well be studies that I've missed, but we hope that we've really tried hard to capture those. First of all, the randomized, control trials, but those are in important, non non-randomized studies. But I will try and dig out the Chisel study and why we didn't include it.
Simon Lo	So, for the only randomized control trial comparing conventional radiation and SBRT for patients with a stage one non-small cell lung cancer. Is a ray, a randomized study and that has, yeah.

Beth Shaw (CEbP) I think I think that's probably why it was excluded, because there was no indication that these were that, they weren't the, the already covered indication.

Simon Lo No! What do we say? Again?

Janna Friedly So stage one non-small cell lung cancer has already been covered in the earlier decision in 2012. So we're not revisiting that or changing the criteria the coverage criteria for there.

Simon Lo So the camera criteria. What has been covered would not be reversed right in a past?

Janna Friedly Exactly. Yes.

Simon Lo Okay and that explains, you know, there are actually 2 randomized trials for spine metastases, spine bone metastases showing positive results strong positive outcomes into the pain control.

Beth Shaw (CEbP) And again that was already covered for the spine mets are covered. So we we didn't look for any more information on spine.

Simon Lo Because it's included already. Yeah. So you know, I think I want to comment about the renal cell carcinoma situation, because actually, I think in terms of stereotactic body radiation therapy. So first, I have to actually, you know, do a disclosure actually, I'm a co-founder of the International like radiation surgery for cancer care network. And you know I'm one of the steering committee members of the International Research Group, and then, you know, of course, I treat stereotactic patients, you know, for kidney cancer. So this is my disclosure, but there's no financial disclosure related to kidney cancer, so I think you know, in that situation, actually, you know, we need to separate out you know, kidney cancer into different groups for the patients of the small kidney tumors, you know, that are potential potentially operable or eligible for radio frequency ablation. You know, of course, I agree. There's no comparative study showing that stereotactic body radiation, you know, is superior to those, but actually, most of the patients getting treated are patients have no other options like those patients are too frail for surgery, and the tumor is too big, or it is located in the middle of the kidney, which you know we call that, you know, it is dangerous to do it, it is too large where it's in a dangerous location. In those patients there's no other option there’s like no cancer treatment or using SBRT to treat that particular group, you know, is need special consideration, because there's such a you can't compare can run a trial, because those patients have no other options.

Janna Friedly Great. Thank you for that point. I wanna do on in the interest of time. I do wanna make sure that we are able to get questions from the committee, and I'm sure as they answer, ask questions they may ask you questions as well. That for further clarifying points. I saw Clint's hand first, and then Christoph.

Simon Lo Sure.

Clint Daniels Yes, this is a question for Beth I was curious. A number of the public commenters mentioned. Did any of the studies included look at that specifically?

Beth Shaw (CEbP) Yes, at least one, and I think it was that head and neck one, if you remember where they specifically talked about reirradiation. I'm just gonna try and find it. I'm pretty sure it was head and neck.

Clint Daniels And then, while you're looking at a follow up, Dr. Lo what would you kind of comment on reirradiation is, does that typically mean after conventional radiation has already been tried? And you know a more fine tuned treatment is needed, or is it repeat SBRT when that's utilized, or maybe both?

Simon Lo So let me explain to you in broad terms so usually after one course of radiation, whether it is external beam, conventional radiation, or stereotactic radiation. So you usually the first time around the tolerance of those organs, in many cases, would have been exceeded. But you know, sometimes, if we can actually limit the radiation dose to those organs to a very small volume, we can push the envelope and retreat a patient, you know, giving the patient to control rather than letting the letting the tumor grow. So in that situation, we need to use a high technology to actually, you know cough the dose around, you know the target. While sparing the critical structures by using advanced techniques, so by advanced techniques is either IMRT or SBRT. But SBRT is the most effective way of doing it, because each time you need to do it, unlike the first time around you need a very rich get set up very robust setup, and every time you set a patient like that, you need a long you know, time slot to do that, and it's actually just not feasible. Sometimes it do it like for 30 times a 20 times. So you do it, you know, 1 to 5 times, and that's reason why, for patients who have prior radiation before actually the only way to achieve any meaningful, in fact, of radiation is to use SBRT in most cases. That's reason why, for re-radiation, though, it's an extremely important cool. I know there's in a lot of it, there's actually not much randomized trials apart from the head next study. But the key reason is because, you know, sometimes it's unethical to give like repeat radiation using a substantive technique, a low tech technique, reserving in the high rate of toxicity. I mean, nobody wants to do that. And the other thing is using chemo mainly a time, it doesn't work. That's reason why I think you know IMRT or SBRT may be, and sometimes protons may be, the only way to reradiate to a meaningful dose while still being able to spare the normal structures.

Janna Friedly And just to clarify that that's talking broadly across cancer types?

Simon Lo Yeah. In general, anybody's site. Yeah. Except for maybe the bone, you know, like the bone, there's actually not much critical structures. Here, but you know, like in the lungs, in the thorax and the abdomen, in the pelvis, in a spine, in the brain you know, you need those high tech techniques to prove a normal structure or otherwise the toxicities will be prohibitive, I was saying, really prohibitive.

Janna Friedly And just to also clarify a follow-up. As currently shown, written the recommendations for coverage criteria in your opinion, that does not cover

	reirradiation sufficiently to be able to reradiation, to to be able to use those purposes?
Simon Lo	Yeah. Yeah, I think it's really important, because I think you know the only way to be able to effectively treat a previously irritated area without hurting a normal t shoot is to use the high tech, tech technique. And that's the, you know best way, and sometimes the only way to do it, you know, like, say, for example, you know, I treat spine patients and brain patients. If you were to irradiate, she's using a regular thing, you know. We'll paralyze the patient.
Clint Daniels	And one last quick. Follow up the this in the state recommendation there are a number of specific cancers they recommended not covering, including renal bone adrenal. A few of these are, would reirradiation be a reason to that it should be covered? In your opinion, Dr. Lo
Simon Lo	I think, for bone, you know, for spine. I don't know what a spine is covered radiation is covered, you know, in the original policy. Spine and brain. In the original 2012 policy was it covered? Others in a case with those complications? I mean indications covered.
Janna Friedly	Spine and CNS were.
Simon Lo	Whether it's first time around radiation, right?
Janna Friedly	That I'd have to ask our.
Simon Lo	Yeah, I think, usually, if they cover the first time around radiation, it's actually even more important indication, you know, for radiation. I suppose it's covered as well. Yeah.
Sophie Miller (HCA)	The 2012 division is silent on whether it's initial radiation therapy or reirradiation. Okay. So it by default. It would cover reirradiation as well.
Simon Lo	So I think you know, pertaining to a question about adrenal and kidney. So one thing is because both kidney and adrenals they're moving organs unless one is using special technique, particularly for the kidney, because kidney actually has a low tolerance. That means you only need a small dose of radiation. Actually, it's completely wrecked a kidney leading to like complete loss of a function of the kidney. And that's reason why, do any way to treat a kidney tumor effectively, using a meet, giving a meaningful those without hurting a kidney tissue is to use high tech techniques that SBRT and, as I've mentioned before. I think you know the recommendations are too blanket because there are different scenarios, for, like tumors that are eligible for surgery, or are they I mean rate, if you can see ablation, or even observation. So I agree you know, there's no comparative study showing that SBRT superior. But, on the other hand, for those patients, with no other options, for you know tumors that are very close to the center of the kidney, not suitable for surgery or radio frequency ablation, the only option is to not treat the tumor which is you know detrimental so I think for that reirradiation is usually not

even considered, because you won't need an irradiating the kidney without that advance technique, because you'll only need a small radiation dose to completely rack the kidney function. Is that like the liver has small reserve, you know. Usually the tumor size relative to the over volume is small compared to the relative size of the tumor to the volume of the kidney has a very small volume compared to the liver.

Janna Friedly Alright. Thank you. We have I have Christoph next, and then Tony.

Christoph Lee Great thanks, Janna, so had couple more specific questions. I'm trying to basically take our recommended, our recommendations from the Agency Medical Director, which are draft. And look at the evidence report just presented by Beth, and try to make some sense of the very specific wording in the current recommendations and I'm looking at both the Liver HCC and oligometastatic draft recommendations and want to ask Beth and Dr. Lo about the number and size cutoffs for using SBRT based on the evidence. So for liver HCC the agency is saying that it should be 5 or fewer lesions, for 6 cm or smaller, and for all oligometastatic disease the agency is saying 3 or fewer lesions in a synchronous setting, and at least for the oligometastatic disease, looking at the SBAR Comet trial, they looked at one to 5. So my question is, is the evidence really pointing to these numbers cutoffs? Or should we not have these number cut offs?

Simon Lo You know, if you allow me, I can make the comment about the oligometastatic, and the other question regarding HCC. So I would say, for oligo metastatic disease. So currently, for I think the most contemporary trials they use 5 as a cut off. But you know, for each organ, not for more than 3, but total of 5, you know, for the whole body, and I think SABER Comet is actually is one of the you know most I think, inclusive, and you know robust trial for oligomets. And there are some histology specific oligomet study, you know, by Dan Gomez from MDN Anderson and by doctor Peneve you know from UT South Western no using like different cutoffs, but I think you know, 5 is actually a very, you know, commonly used cut off for modern trials, but you know not more than three lesions in one single organ, because the concern is, if you have like,3 lesions that are separate from each other. You know the radiation dose bridges between the lesions can actually exactly can, you know, wrap the organ. That's reason why the limits is three. But I think you know 5. You know, 3 actually was the cut off, maybe 10 years ago, you know, to trials. But right now you know most of the trials they use, you know, 5 as a cut up and say, for example, you know, like dating back I mean, when we look at pediatric trials. Actually they in those in actually the pediatric trials for metastatic lesions, actually allow 5 metastatic lesions. So I think 5 is actually a more reasonable number compared to three. But 3 is for each organ, you know, like you cannot have more than 3 metastatic in each organ, but total so pertaining to ACC, I think you know I completely agree with Dr. Smith Apisarnthanarax and you know he's one of the top liver cancer expert in a country. In the clinic trials actually it most of those patients they got tumors much bigger than like, you know, 6 cm nd actually in the R2U trial, that I think they're, you know, preparing to publish and

	just comparing serfrininib versus SBRT, there's a benefit to the addition of SBRT, actually, the radiation dose prescription is based on the tumor size, so they make sure that you don't, you to give the maximum amount, but not exceeding what a liver can receive, so they use like a sliding scale to determine the dose. So there's no dose limit. And you know, in a trial the median tumor size is 8 cm, so I think you know it.
Janna Friedly	So Dr. Lo, can you clarify, this is the second time that this trial has been mentioned It's a, it sounds like it's a new trial that has not been published yet. So it's.
Simon Lo	It was a presented but not published. I mean, they are preparing to publish.
Janna Friedly	And you're not in.
Simon Lo	But it was precise in multiple, like a top meetings like ASCO and and ASTRO.
Janna Friedly	And that is not included in in the I just wanna clarify that's not included anywhere in.
Simon Lo	Yeah, because it's not yet published. And actually, if you want to, I can put it in chat box. Actually the trial group lso, I think, put that on the website. RTG 1, 1, 1, 2, I think, if I remember the name correctly. So in the S, yeah. And and are you on the oncology website.
Janna Friedly	That that would be helpful.
Simon Lo	I think. Let me put it, let me copy, and paste is in ASCO.
Janna Friedly	Great.
Simon Lo	So ask, is it top oncology meeting, so let me put it in a chat box, and you can take a look. Let me send the chat to.
Janna Friedly	Christoph? Does does that address your question, or is there?
Simon Lo	Yeah, you can take a look there. So in that trial, actually, this is based on the novel approach invented by the group Inertia of Toronto. Princess Margaret Cancer Center, Dr. Laura Dawson, you know, uses the sliding scale to determine the risk of radiation induced liver disease by, you know, like you know, when she was at U of Michigan, she designed a normal tissue toxicity model. So basically, the composite radiation dose to deliver would determine the risk of toxicities. So based on a size, if you reduce the dose, you can limit the toxicity to within the acceptable level, and everybody can get treatment.
Tony Yen	Hey, Janna, just quick question for me. Are we supposed to be taking into account unpublished studies, too, when we make our decision.
Beth Shaw (CEbP)	I would just say that when we, when we do the reports, we do not include unpublished studies, and we did not include conference abstracts. So that is not part, you know. There's always a cut off at some point.

Tony Yen	Yeah.
Simon Lo	But I think this.
Judy Zerzan-Thul (HCA)	Yeah, and this is Judy. I think we don't include unpublished studies because they haven't gone through peer review. And we don't know all the details about sort of who's sponsored them, and you know all those pieces if this is an important study, we can always do rereview and bring that back once it's out. But yeah, I would, I would encourage you to stay away from the unpublished studies, even though it sounds like this is a, an area of continuing knowledge. I one of the reasons why we rereviewed this is because there has been a change, and there's been more published studies, and I suspect we will rereview this again in the future, as, as the evidence evolves. But we really need to have the whole. The whole thing laid out more than just an abstract, I think, to consider.
Simon Lo	So one consideration is, I think, the reason why one is limiting to 6 cm is mainly it's a safety issue, but actually, you know, there are published studies from Princess Margaret Cancer Center by Laura Dawson, showing that using this approach, actually, there shouldn't be any size limit does need to change radiation, those to make sure that you are confining the amount of liver being treated to a safe level. So I think the size limit, I think, is the main issue, because most HCC patients, you know, when they were diagnosed they got pretty big tumors in general.
Janna Friedly	Alright.
Simon Lo	It's more to tumor than symptomatic.
Janna Friedly	Thank you any that's helpful. It's helpful to know what the landscape is and what's on their horizon in terms of the, the research as well. But that's did you have another clarification for a.
Beth Shaw (CEbP)	Yes, so I was just going to kind of round out this ongoing studies. We do have a section in the report on ongoing studies, and just in summary, we identified 46 ongoing randomized control trials. So that's just, just randomized controlled trials this 46 of them that we found, and some of them are actually in areas where we don't yet have comparative data. So there's like ongoing trials in both breast and ovarian cancer. So I think Judy's point about, you know, this is an area where things, things are very different to where they were in 2012, and they may be very different you know, next year in in 2 years time.
Janna Friedly	Alright. Thanks, Beth. Jonathan.
Jonathan Sham	Thanks, Janna. First is thanks Beth for really outstanding review, and are really herculean effort to cover such a broad, you know, as a surgical oncologist I understand how many facets each of these disease processes and kind of present and, and so thank you for attempting that. I guess I have a comment and a question. I guess. First, the question to the perhaps the best of the AMD. You know, each of these disease states have very particular kind of treatment courses,

	and in times when SBRT could intersect a patient's treatment course, I'm thinking, neo adjuvant, adjuvant defensive therapy, consolidative therapy and clearly I realize with limitation how detail we can get. But you know, for I'll just say pancreas cancer, just cause I'm most familiar with that. For example, you know there's this kind of broad statement of it's covered for locally advanced pancreas cancer. But really doesn't say anything about when in the treatment course it is covered. And certainly there, like upfront treatment with SBRT would never happen in the clinical setting is not substantiated by data, and it always happens after chemotherapy or in a consolidated point, is, I guess, is it the agency's role to get that prescriptive in kind of how we outline coverage like I guess how detailed we wanna get, because again, for each of these again, it wouldn't make sense to cover it in certain circumstances, and it would in others. And I just I don't want to get sense of of of the group's thoughts on that. And then just the comment is about oligometastatic disease again, this is more of a perhaps structural relic from the 2012 report. Possibly. But you know oligometasteses, or oligometastatic disease really means a lot of different things, you know, Doctor Lo, I think you'd agreed oligometastatic, renal versus adrenal versus biliary track are completely different diseases and therefore SBRT should be implemented in completely different ways in those disease types. So I guess I have a little bit of concern lumping them all together in a coverage statement given, I mean, as I think. Was it Christoph? Maybe it just already pointed out, like it's already inconsistencies with oligomets, HCC, you know, versus others. I just worried that lumping them altogether really kind of it will lose importance, granularity in efficacy, safety in those cancer types.
Janna Friedly	Great. I think it may be helpful to get Judy's perspective I think a little bit about, about the you know, from their perspective, the granularity of the recommendations that they're looking for from us. Because I agree. I, I myself am struggling with the, the discrepancies between the recommended agency recommendations versus the, the literature, and what we're hearing in just in terms of the some of the very specific criteria. So what I think a little bit of broad context would be helpful, I think, for the group.
Simon Lo	So in terms of clinical trial, you know, I think sometimes.
Judy Zerzan-Thul (HCA)	So can I. Can I talk first, Dr. Lo? Thanks. This is
Simon Lo	Sure.
Judy Zerzan-Thul (HCA)	Dr. Judy Zerzan-Thul, I'm the chief medical officer here at the Health Care Authority, so I'm not, I'm you know, part of the surrounding bit of this committee. So that's why we didn't have instructions earlier for myself and others on this call. I do think the part of the reason for this rereview is to get granular into these areas because it's not clear where this technology is better than other technologies. The harms seem to be low, which was part of the reason that we decided to do this, of

whether this was more harmful than other types of radiation. But we really do want to get at where is this more helpful than other parts? And where should it be used versus, versus not? The, the point of this committee is to use evidence of what it is published. And so we have, as usual, our contractors at the Center for Evidence-Based Policy this time, but you know we have 3 sets of contractors, they put fairly tight inclusion and exclusion criteria to answer the questions that we have. So that there are sometimes trials that aren't included in and there are reasons for that. And there's also part of this process the public posting of the draft report that allows people at a time to say these, these studies didn't get in why is that? And then we sort of respond to that. So I am a little bit worried that we're getting sort of off track and out of scope of what, what this review is focused on, and what will be most helpful for us.

Jonathan Sham — Okay, thanks, Judy. I guess maybe I'll be a little bit more specific in my questions. I think it might be helpful. So again I'll just go back to pancreas, the AMD recommendation for pancreas cancer. I think it's because it's it's pretty simple and it says it's a cover benefit for locally advanced pancreas cancer. Now again, it doesn't make a statement whether that's first line, second line and setting a failure of systemic therapy, consolidative therapy. And again, you know, I realized that we didn't get kind of all into granular data, but at least for, for each of these disease sites there's going to be 5 or 6 specific settings that could we could comment on, and certainly I don't, certainly not today we don't have time, but certainly that green letter is not presented in the current coverage recommendation. So I guess my question is for the purpose of today's meeting within each disease site, how detailed do you want us to get? Because again, each of these is kind of almost a meeting in and of itself.

Judy Zerzan-Thul (HCA) — Yeah, no, that's true. And I guess there is sort of a balance of like a high enough level like it shouldn't be like, for I guess that granular, but it needs we sort of sort of pulled out these different kinds of cancers where there seem to be themes are sort of a proponents of evidence to try and try and connect the evidence around this. And so I think granular to the level of, of these different types of cancer, because I think that's sort of the easiest way to get at it, and that we had lots of discussions about the oligometasteses, because, because some of them are in cancers that are excluded from the review. But it does really seem to be in the evidence that they're that there is help by use of this therapy in those cases, and so it is., it is a little bit of maybe arbitrary sort of dividing lines by these categories, and I think the committee's charge is to is to try and use the evidence to get to recommendations that are sort of the, the goldilocks, part of too broad into narrow, because too narrow will be hard to implement for us. But some details in what should be covered and what shouldn't be covered, because the evidence is still developing would be very helpful. I don't know, Sophie, if you wanna add anything to that?

Sophie Miller (HCA) — I think my only other addition, and I agree with everything. Dr. Zerzan said, is that some of the generality of the recommendations came from other payers as a kind

	of example of how recommendations are made for coverage from other payers, and I think the other payers that I evaluated didn't get to the details of whether it would be neoadjuvant, etc. that was usually left up to the up to the oncologist or the radiation oncologist treating the cancer.
Judy Zerzan-Thul (HCA)	Yeah, and I think the part I think we included in all of the recommendations, although now that I'm saying that I'm not sure about that, this is used in conjunction with a Tumor Board, because it really is that multidisciplinary, what's the best part and so we're, we're sort of counting on the Tumor Board to help guide those kind of individual decisions, and that that is part of that is part of the power of, of doing it this way.
Sophie Miller (HCA)	Yes, tumor boards are recommended for every type of cancer.
Simon Lo	So actually, I have to make some comments, because actually, you know how the radiation is sequenced, sequenced with the systemic therapy really depends on the individual patient situation. Sometimes if the systemic diseases progressing rapidly but there's a local issue, you need to treat with SBRT. Sometimes we may be forced to do it concurrently, you know, if it is not of, you know, extremely high risk, like, you know, immunotherapy. But sometimes you know, because some drugs, you know, when combined with like a VEGF inhibitor when it is combined by SBRT, if you're treating and abdominal site, it may actually cause perforation of the visceral organs of the tubular organs. In that situation we can only do it, you know, like sequentially or sandwich in between different cycles. So I don't think we can actually, you know, make a generalization or guidelines, because it depends on a patient's clinical scenario and actually, we are way behind our European colleagues, and they have published actually the recommendations of the concurrent use of targeted therapy and immunotherapy with the SBRT. You know, for I think oligometastatic and non-small lung cancer is from Eastern European Society for Radiation, Oncology and ASTRO hasn't done it yet. This, you know those were European guidelines.
Janna Friedly	Great. Thank you. Jonathan, did, did you have any other follow up to that?
Jonathan Sham	Yeah, I mean, I guess just so it's clear that the committee and myself in particular, kind of as we make these decisions about the data, we're just making a statement that we think that it should be covered at any stage of the patient treatment course for this particular disease at the discretion of the physician and I guess as long as we're comfortable with that last comment, the timing being left at the discretion of the treating physician you know we can make a determination based on each disease site as laid out.
Simon Lo	In a clinical scenario.
Josh Morse (HCA)	Janna, this is Josh. You know this period this conversation has been good. We've move beyond the evidence report committee, question, answer for time with the center and you're beginning to converse about coverage issues and there was a

	break in there so I just wanna check in with you on the timing and use of the time here, with the center.
Janna Friedly	Yeah, I, I'll just ask if anybody has any other specific questions for Beth at the OHSU team before we break for 10 min and then continue our discussion about our decision and evidence. Okay, so with that, why don't why don't we break for 10 min? We'll come back at 11:40, 9 min, I guess 11:40, and then we'll, we'll start our discussion or continue our discussion about the coverage.
Josh Morse (HCA)	Thank you.
Janna Friedly	Okay. Great. So thank you, everybody. If you yeah, turn on your video so that I know that everybody is back. Great I think we have, who am I missing? Jonathan? Jonathan, are you here?
Val Hamann (HCA)	He just came back in and is transferring to a panelist again.
Janna Friedly	Okay. Great.
Jonathan Sham	Yes, I'm here. Janna, thanks.
Janna Friedly	Okay, perfect. I just wanna make sure we had everybody. Okay. Great. So you know we are now at the point of discussing the, the evidence, and starting to craft our decision and so I just want to remind everyone that you know we've had the evidence that you know we've had the evidence report and and we have our clinical expert, Dr. Lo, who is still here. Is he? Actually don't see him?
Sophie Miller (HCA)	Here.
Simon Lo	I'm here. Yeah, I switch on my camera. Yeah, yeah.
Janna Friedly	Here. Okay. Sorry. Sorry. I just can't see. And so, and you know, really, he's here as our expert to help us guide us in terms of some of the clinical clarifications and questions, so we can use him for his expertise as we as we make these decisions. I know that it's, this is a challenging topic given the breadth of, of the topic in the number of different categories of, of cancer types that we are, we are looking at. So I will try to be as efficient but thorough as possible during this this process, so during this this process, so bear with me as this is, is, this is a challenging from an organizational standpoint. So, so you know, I wanna just open it up to the group one more time to see if there are any other questions that have come up or thoughts or concerns before we, you know, start using our decision tool to think about crafting our decision. Clint?
Clint Daniels	Yeah, I had a question about cancers, that where there's no determination made. So in that in the 2012 there was no determination on small cell lung cancer, if I read correctly, and some of the public commenters brought that up, and I was just curious how, how the agency handles it. If you know someone does request treatment for that?

Josh Morse (HCA)	If it was in scope, I'll try to take this Clint. Then it should have been addressed with a decision meaning it would have been, if it's not covered, it would be not covered if it was out of scope, then the policy doesn't apply, and the agency would address requests through a medical necessity process.
Clint Daniels	Okay, so sort of a case by case basis for?
Josh Morse (HCA)	Yeah, if it was in the scope, though, the committee makes a decision in that typically means, if you know, if there wasn't evidence for it, or if there was evidence that it wasn't effective, you know, I'll have to look back at that decision which I'm trying to navigate.
Clint Daniels	Okay.
Janna Friedly	Great. And just as a clarification that the recommendations for this decision from the agency are the small cell lung cancer is not covered as a primary, as the SBRT is not covered for treatment of primary tumor for small cell lung cancer.
Sophie Miller (HCA)	And this is Dr. Miller. I would just want to clarify that patients can still pursue treatment under a clinical trial, this supply to SBRT outside of clinical trial settings.
Janna Friedly	Okay. And is, is that language something that we need to include in our coverage decision just across the board about clinical trial participation. Or is that, is that just understood?
Sophie Miller (HCA)	I don't believe it needs to be included in the coverage policy.
Janna Friedly	Okay. Great, thank you, Christoph. I think I saw, did you have a hand up?
Christoph Lee	No, just to clarify. That means today we have to make a coverage decision on renal, adrenal, bone, small cell lung cancer? Well, all the things are listed, we have to make a determination?
Josh Morse (HCA)	Those are in scope. So yes, they looked for the evidence for that.
Christoph Lee	Okay.
Josh Morse (HCA)	The process is based on that systematic review looking for the best available evidence so it it's not possible to steer around that. If that's.
Christoph Lee	Okay.
Janna Friedly	Yeah, and so do you want to show our, our decision guide on the screen as a reminder? We have, you know, so just to remind you all, as you all know, that we really are focused on 3 different components of the evidence to make those decisions. So is it safe? Is it? Is it effective, and does it provide value and improve health outcomes? And so I want to just sort of as a guiding principle steer us back to that our determinations really have to be evidenced based, and that determination should result in in health benefit as our sort of guiding principles in health benefit as are sort of guiding principles. So when we look at our decision

aid, we typically will do, we'll go through each of the different decisions that we need to, to make based on and get an idea of what the evidence is telling us, based on safety, efficacy, and cost effectiveness, so that's how we, we are organizing our, our votes today. So, and I think given, given that it is so I think the other part of this, Josh, I think you have down below our table, where we show each of those different cancer types and the comparators, so just to orient people that we will be doing these votes, I think, based on, you know, speaking to each of the different cancer types, I think there's, there, it does not appear to be a way to lump these altogether and we do need to address each one of these. So just wanna make sure that you're aware of that.

Josh Morse (HCA) Right. So we do have, we have pre-organized that. Melanie, can you bring up that other document?

Melanie Golob (HCA) Yeah, happy to do so.

Josh Morse (HCA) Thank you, and I'll stop the share here.

Janna Friedly And then, as we mentioned earlier today, we are going to be using the polls. But we'll see how it goes with you know how, how time consuming that is versus the, the chat function. So bear with us as we as we go through this.

Simon Lo Just wanna clarify. I'm not, I'm a non-voting panelist right today.

Janna Friedly Yes, absolutely. So your role here as we do our discussion is to help clarify. We often times given that this is not the primary expert clinical expertise for many of the members of the committee is to provide clarification based on your clinical experience about some of the technical details and things like that. So we may be calling on you for specific questions as we go through this. Okay, so, so I think, usually what we do at this stage is to go through one by one each of the different conditions specifically focus on safety first and get an idea of where we are standing as a committee in terms of what the evidence is showing us, based on what was presented in the report and the presentations today. So I think we should proceed with going through this process, starting with safety and as you'll see, they've organized this based on comparators, I think, Josh, if I was the way I was thinking about this was that unless, unless it is critically important to separate the different comparators for the purposes of this, these sort of straw votes, that we would include those all you know, as in one, in one comparator.

Josh Morse (HCA) I agree, Janna, you know I think this is a frequently challenging part for the committee. But this is really just a taking the temperature of the group about whether you found where your opinion lies on the amount of evidence compared to what was available as comparators in the systematic review.

Janna Friedly Great, and, and then, just to clarify with safety this always comes up for me as I'm thinking about this so unproven, I think, is clear that means that there's not enough evidence to know less means that SBRT is less safe than these other comparators. More and some or more, and all means that it's the evidence shows

	that it's more safe in some or all of the evidence just to be clear. Okay, so with that, we can, maybe we can start with our first poll for prostate cancer and safety.
Val Hamann (HCA)	So we had pre-populated these as have like by condition, and so prostate, would have safety, efficacy, and cost effectiveness together. So is that going to be too much to vote on all 3 at one time?
Janna Friedly	Oh, okay, so that's how you set it up.
Val Hamann (HCA)	Yeah, just ahead of time. We tried just because there's so many.
Janna Friedly	Yeah, I'm.
Val Hamann (HCA)	And I can launch it, and you can look at it.
Janna Friedly	Yeah, I am in favor of doing those together. So we so we can handle it by cancer type go through those one by one rather than by, by the, the other. The 3 categories that makes sense to me. Does anybody else feel differently from the committee? Or is that okay to go one by one?
Josh Morse (HCA)	Janna, if I could make an administrative statement here.
Janna Friedly	Yeah.
Josh Morse (HCA)	So we're gonna disable the chat for the remainder of the meeting we switched to Zoom this meeting as we've come out of the public health emergency in our agencies are trying to consolidate the way we do hybrid or virtual meetings. The chat, function, you know, if we were in a public space at the Conference center at SeaTac, we would not have that. We would not have a chat function like this, this is not an audience participation meeting. There are opportunities for the audience to participate in the public comment portion it, but the chat is becoming a distraction at this point, and it's adding information that is not meant to be part of the process. At this point there will be a comment period after this meeting, when a draft is published. So we're gonna disable the chat for now, and we'll be more clear about the application in the future. Thank you.
Janna Friedly	Great. Thank you. Okay, so why don't we put up the poll for prostate cancer? And we'll give people a moment to fill this out. And again, this is just for the committee, the voting committee members.
Christoph Lee	And are we voting for safety, efficacy, and cost?
Janna Friedly	Yes, so we are doing this for all 3, for prostate cancer at this time.
Christoph Lee	Okay. Okay.
Janna Friedly	And again, this is these are straw polls, just to get a sense of where we are thinking and leaning as a group, and we'll have more discussion when we come up with our coverage decision. And so let me know when we have all votes in.

Val Hamann (HCA)	Looks like we have 6.
Sheila Rege	And Janna, I am abstaining.
Val Hamann (HCA)	We have 6, so I will be ending the poll. And are you ready to go on to lung?
Janna Friedly	I? Yes, yes, we, we can just go through them all. Okay, so I was, gonna say, it would be nice to see what the results are. There, there, there they are. Okay, great. So we have for safety equivalent 83% more in some 17% efficacy, 33% equivalent, 67% more in some, and then 83% unproven for cost effectiveness and 17% equivalent. Okay, so let's go ahead and go on to the next one. So lung, answer.
Melanie Golob (HCA)	I just wanna reiterate these questions are just on safety. And then we have a separate pool for efficacy, and then a separate one for cost effectiveness for each condition. So I just wanted to reiterate that to the group.
Judy Zerzan-Thul (HCA)	Actually, this has safety, efficacy, and cost effectiveness altogether.
Janna Friedly	These are all together.
Judy Zerzan-Thul (HCA)	Yeah. But what's shown up is just safety. So it'll take, I think staff, a minute to put this into the table.
Val Hamann (HCA)	And we have 6 votes, so I will be ending this poll.
Janna Friedly	Okay, great. So we are 50, 50 split in safety equivalent and more in some. And then 33% equivalent for efficacy. 67% more and some cost effectiveness, 83% unproven, 17% less. Okay, and we'll move on to pancreatic.
Val Hamann (HCA)	And we have 6, so I am ending the poll.
Janna Friedly	Okay, so here we have little agreement. We have unproven 17%, 33% less safe, 33% equivalent, 17% more safe, so clearly, less consensus. There, efficacy, equivalent and more in some 50 50 split, and then a hundred percent unproven in terms of cost effectiveness. Okay and then the next is liver.
Val Hamann (HCA)	And we have 6, so I will be closing the poll.
Janna Friedly	Okay, so here we have equivalent 83% for safety and 17% more safe. For efficacy we have 67% efficacy is equivalent, and 33% more in some, and then cost-effectiveness, we have 83% unproven and 17% less. Okay. And then the next is oligometastatic.
Val Hamann (HCA)	And we have 6, so I, ending the poll.
Janna Friedly	Okay. Again, not as much consensus here with safety 50% say more in some 17% each for unproven, less, or equivalent. And then efficacy we have 17% unproven and more in some 83%. And then unproven cost effectiveness in 83% and more in some for 17%. Okay. Renal is next.

Val Hamann (HCA)	And we have 6, so ending the poll.
Janna Friedly	Okay, here we have for safety unproven 50%, equivalent 33%, more in some 17%. Again less, some less consensus and then for efficacy, we have unproven 67%, less 17% equivalent, 17%. And cost-effectiveness, 100% unproven. And a little more variation on safety and efficacy.
Val Hamann (HCA)	And we have 6, ending the poll.
Janna Friedly	Okay, here we have for safety equivalent 67% more in some, 33% efficacy unproven, 33% less, 17% equivalent, 50% and cost effectiveness, a hundred percent. Okay, so adrenal.
Val Hamann (HCA)	We have 6, so ending the poll.
Janna Friedly	Okay, 67% unproven, 33% equivalent for safety. Efficacy is 83% unproven, 17% less and then a hundred percent unproven for cost effectiveness. Okay, so here we have bone cancer. Just wanna clarify that this does not include spine, that was the prior coverage decision that was not included in this report.
Val Hamann (HCA)	And we have 6, so ending.
Janna Friedly	We have for safety unproven 33%, equivalent 67%. Efficacy 50% unproven equivalent, 33% and more in some for 17%. And then we're cost-effectiveness unproven 83% and less 17%. Okay. The, the last group that we have here is melanoma.
Val Hamann (HCA)	6.
Janna Friedly	Okay. Here we have unproven 83%, 17% equivalent for safety. Efficacy is 83% unproven, less 17% and cost effectiveness a hundred percent improving. Okay. Okay. So we've, we've gone through each of the different types of cancer on this list. Having gone through this now, and it seems like for some of the cancer types we have more consensus than others. Maybe you know, it'd be helpful, I think, to go around with our group and see just some, some general comments or thoughts about how you're thinking about this. Now, having gone through that process of going through one by one in terms of the evidence, and where you're, where you're, you're thinking about this. So, I can call on people. It would be helpful to get people's perspective. Okay, go ahead.
Jonathan Sham	Yeah, sorry. I have some thoughts, but sorry I just joined from another computer, because my Internet just came back. Val, could you just push me over to panelists on the other side and press? Once I can share screen, I'm happy to chat, Janna.
Val Hamann (HCA)	Yes, you're being transferred now.
Jonathan Sham	Sorry about that. Can you hear me? Okay.
Janna Friedly	Yup! We can hear you.

Jonathan Sham So I guess just to kind of expand upon my earlier comment. I realize this is a really difficult task that's kind of been laid before us, but I would, I guess generally speaking, advocate for being a little bit more prescriptive in our guidance. You know again, I think, that you know the role for us in some regards is not only to evaluate, you know, safety, efficacy, but it's kind of put guardrails on when these things should be used, these technology should be used. And so I think for some of these diseases, blanket approvals, leaving it up to the discretion of the providers, really doesn't achieve the goal that I certainly the that I think, is kind of laid at our feet and it's kind of our mission as part of this committee, so I guess as we go through each one, you know, I think some have some particularities that have been kind of laid out in the sample policies, but I think others just are gonna need a bit of work and we're just have to take them one by one.

Janna Friedly Yup, absolutely. I agree with you. Tony?

Tony Yen So, I am not a radiation on call just by any stretch of the imagination. So I really do need to rely on that evidence that I'm really trying to make all the decisions that I've made so far looking at the evidence report and really not a unpublished information is the bottom line. I have to say personally, just a little bit of a challenge to keep all these things straight I'm constantly looking back and forth, and the evidence report to really keep track of everything that's going on and paging through things constantly. But that's really how I'm making my decisions over here. Really based on the evidence as best as I can.

Janna Friedly Yes, I agree. I have 2 big screens open in front of me, and I'm constantly juggling back and forth between knocking

Tony Yen Yeah, so my eyes are moving I'm sorry about that. Okay. I'm constantly looking around.

Janna Friedly I think we're all on the same, the same boat here. Absolutely. Okay, Laurie, do you have any comments?

Laurie Mischley Only that I also have multiple screens happening here. I think I'm inclined to not be terribly overly prescriptive with the size of the lesions or the number of the lesions and things like that. I certainly acknowledge that there's going to be some judgment calls that have to be made, and medicine needs to be personalized. Uh, I was struck the number of times the experts mentioned in renal carcinoma that there just is nothing else, and it's that really got to me in that as heartbreaking as that is, that's not enough to sway me over a lack of effectiveness data or safety data. And so I'm you know as much as it is nice to be able to offer patients something, I think it's important for me to again go back to the evidence base and separate what I want, and what would be nice and what's clinically helpful from what the data says, actually works. And so I'm trying to keep those in mind. And just acknowledging the dynamic nature of the field. I was really struck by the, I

think, ongoing 42 trials and realizing that this is very much a work in progress, and we'll probably be back here in a couple of years, having rereview.

Janna Friedly Yeah. Great. Clint or Christoph, any other comments.

Christoph Lee I feel the same way as Laurie, you know. I don't wanna be overly prescriptive. I want the multidisciplinary teams to have some freedom to personalize their treatment regimen, especially in very rare circumstances, where we're never gonna have trial data and the circumstances where it's the only option right? There's no other alternative and this is the only option on the table. So I agree we have to stick with the evidence. But I also realize that these are very difficult situations, that require multidisciplinary conferences, and if the determination by a team is that this is the only option I'd hate to take that off the table. But yeah, it's where I'm at.

Clint Daniels This is Clint. I don't really have anything to add that others haven't already really eloquently said, I agree, you know, stick to the evidence, and it seems like there are pathways for the cases who maybe don't fit perfectly for reviews as well.

Janna Friedly Okay. Great. Okay, Tony is still up. Is that up for a reason?

Simon Lo Yeah.

Janna Friedly Or was that, yeah, okay, okay, that's okay. And then.

Tony Yen No, sorry I didn't blow my hand yet. I apologize.

Simon Lo To, if I'm allowed to make it, just a short comment and actually, I think when you mentioned about the lack of evidence, I think you know, yeah, there's no randomized studies, because actually, you know, for kidney, because basically, you know, those patients, there's actually, you know, if there's no other alternative, there's actually, it's between actually doing nothing versus tumor radiation. And actually, there's a safety data, because there are actually, multiple trials, you know, looking at the safety of the treatment, then actually, I think there, at least, I think 1, 2, 3, 4, you know 4 trials, you know, looking at this safety. So actually, it is, you know, in those trials the treatment is determined to be safe and the second thing is in terms of efficacy, I think there some trials looking at one reason, phase 2 trial, looking at using the straight at kidney cancer. And they know, see over like 85% local control. So I think, if that is to the reason to completely say that, you know this treatment is not effective at all, of course, you know, there's nothing to, there's no comparator in those studies. So I'm just try to understand where the panel is coming from in terms like the efficacy, because actually, there are multiple trials showing that actually, the local control is, you know, between 85 to 95%. Just wanna make sure that you are aware of, you know, those studies. And actually, those studies were not include it, you know, in the analysis. And I knew that the ideal situation is you have the huge clinical trial, you know, prospectively enrolling patients and determining the, you know, have a standardized treatment, but I think so far all these trials they're relatively small. I think the maximum number of

	patients is a few dozen of patients, and I think one of when it talks about safety, one of the big studies, the pull analysis pulling patients from, you know, or around the world, 190 patients, and it was recently published in Lancet Oncology, is like a top oncology journal, you know, shows that the local controls that 95%, you know, with long-term follow of one in 5 years. Are those not like as perspective study. But again, I think you know, there's some data out there. So I'm not seeing that this should be a standard treatment, but in patience with no other options I didn't think this should be disregarded. Of course it cannot replace like surgery or RFA tor simple patients, but for patients, with no other options, I think out there multi-disciplinary tumor board discussion, you know, this can be considered. It's only after, like multi-disciplinary tumor board discussion.
Janna Friedly	Great. Thank you. That's helpful context. Huh?
Simon Lo	I think this is my take on it, because actually, a lot of the most important information actually has been omitted, you know in the report, because those a lot of those patients who got enrolled were medically in operable patients who were not have been allocated for anything else. And that's just why those patients when wrote those trials and in those trials, it show that the local control, you know, ranges from 85% to, you know, over 90%.
Janna Friedly	Yeah, and I think as we as a committee, as you can see, we are are trying to balance, you know, making sure that we take the context and the clinical context. But really focusing on the evidence as, as presented to us with the with the very specific criteria from the report. So I wanna make sure that we are careful about you know that we that we have done a very thorough process in terms of sifting through the evidence and that that's been synthesized in in the report for us. So at this point I know we are running a bit behind, and I had hoped that we would get through our our coverage vote before we break for lunch, but we are running a bit behind. Does the group want to go ahead and, and do a vote on, on each of these before we break for lunch and then come back and discuss them? Or do you feel like you need a break before we, before we get to that next step? Any, any preferences from the committee?
Jonathan Sham	My preference would be to vote.
Tony Yen	I feel fine with voting.
Janna Friedly	Okay, alright. Let's do it then.
Val Hamann (HCA)	Alright. Yeah. So again.
Janna Friedly	Yes.
Josh Morse (HCA)	So Janna, can I just ask point of clarification? So you're gonna take a kind of a straw vote on direction of coverage. Is that in then work on conditions after that, before moving to a final vote?

Janna Friedly	Yes.
Josh Morse (HCA)	Okay, thanks very much.
Christoph Lee	So, Janna, just a quick question, should we not focus on the details of the current drafts, then just the overall, are we gonna cover or not? In some context?
Janna Friedly	Yeah, so it's yeah. So the the poll is going to be not covered, covered with conditions or covered unconditionally.
Christoph Lee	Okay.
Janna Friedly	And so we can get an idea again of where the committee is that this is not the final vote. But this is, it will help frame the discussion as we go forward in terms of conditions, not for those that that we need to create those conditions for.
Val Hamann (HCA)	Okay. So we'll be going in the same order with prostate being the first. We have 5. So closing, did you want to see the polls or the results, or just go on?
Janna Friedly	We can, you can just flash them up quickly.
Val Hamann (HCA)	Okay.
Janna Friedly	Okay.
Val Hamann (HCA)	Moving on to Lung. Okay, closing the poll.
Janna Friedly	Okay.
Val Hamann (HCA)	Moving on to pancreatic. Ending the poll. On to liver. Ending. Okay. Ending the poll. Ending the poll.
Janna Friedly	This is our first one with mixed actually not covered 33%, covered with condition 67%.
Val Hamann (HCA)	Ending.
Janna Friedly	Yeah, again mixed, not cover 67% covered with conditions 33%.
Val Hamann (HCA)	Ending the poll.
Janna Friedly	And mixed. 67% not covered, 33% covered with conditions.
Val Hamann (HCA)	Ending the poll.
Janna Friedly	83% covered with conditions, 17% not covered.
Val Hamann (HCA)	Ending the poll, and this was the last one.
Janna Friedly	Mixed 83% not cover 17% covered. Okay, so it looks like we have some consensus on some of the conditions, with coverage covered with conditions. We did not, nobody thought that there should be coverage unconditional coverage for any of the conditions, and then we have a few a handful where we still are a bit mixed in terms of our not coverage versus cover with conditions. So, okay, so I would, I, I

think we should take a short break for lunch, or whatever we need to do. And so we, we had planned to come back at 12:30. Why don't we take a, if it's okay, take a 15 min break and come back at 12:45? Okay. Welcome back. Do we have everyone here? Looks like 1, 2, 3, 4, is Jonathan? Yep, you're here. Okay. Great. Okay. So now that we have done the straw polls, I think I would recommend that we that we start to go through condition by condition, and, and work through each one, and see how far we can get in terms of you know, getting consensus, and then we can do our final votes. Is, Josh, are, are you here? I just wanna make sure I'm not starting without.

Josh Morse (HCA) I'm here.

Janna Friedly Okay, good. So you can help keep me in line and, and make sure that I'm going through the process correctly. So, so that's what I would recommend. And, and we did have some consensus, at least in terms of coverage with condition, for, for some of the, the cancer types and so I think starting with those would be helpful. So. Great. Thank you. Yeah. So, so we we clearly have consensus on the first 5. So, and then, when it comes to renal, head and neck, adrenal, bone and melanoma, we have a little bit less consensus there. So I like to start with some wins. And so let's start with prostate cancer. If that works okay and talking through the coverage conditions that we would recommend. Do we wanna, would you be able to pull up on the screen just as a starting point for discussion the agency recommended language from the presentation earlier today? And I'm pulling these up on my screen here.

Josh Morse (HCA) So as I usually do. I have.

Janna Friedly Well here, so on top of it.

Josh Morse (HCA) Put these into, you know, just a working draft, and can modify type as you go.

Janna Friedly Perfect.

Josh Morse (HCA) That's helpful. Hopefully you're seeing a screen that says has the draft on it?

Janna Friedly I am. Yes, I am again going through my multiple screens that I haven't looked at different.

Josh Morse (HCA) Okay. Great.

Janna Friedly Comparisons. So anyone on that group have any initial thoughts about this language in terms of the risk, the cancer risk as well as the, the definition of risk for coverage?

Jonathan Sham Yeah, I'm happy to weigh in Janna. So it seems like, you know, we all, we all agreed, covered with conditions which have to kind of spell out what the conditions will be. I think the selection of the subset of patients with very low, low, and intermediate risk does make sense, both kind of oncologically and with the data. You know, you would imagine that a local therapy would be less effective for

	a higher risk disease that's more likely to spread metastatically and that's what the data certainly presents on the data report on page 21 where all the confidence intervals cross one in the higher risk group. And so I would support the subselection of the very low to intermediate risk group as our kind of condition.
Janna Friedly	And this definition, as defined by NCCN based on stage Gleason score and PSA level is specific enough, or in terms of the criteria clear enough in terms of the criteria, for that is that the accepted?
Jonathan Sham	Yes, I know we didn't wanna get to prescribe, but I think that is, that's broad enough. I think, gives people that up will the room to tech people into those categories based on those criteria.
Tony Yen	Hey, Jonathan, this is Tony Yen. I'm curious, I think you probably have way. More experience on this subject matter than I do. But would, do you think that just having a multi-disciplinary team analysis like, you know, a tumor board would be sufficient with something like this because I think the tumor board is at least from my perspective, would only, perhaps only refer people with a very low or low intermediate risk prostate cancer? I just want to check in with you as this isn't my scope.
Jonathan Sham	Yeah, I think. I mean, you're asking kind of what I was asking before. I don't, I don't know what the agency is looking for with these recommendations.
Tony Yen	Oh
Jonathan Sham	Because if we just, you know, at on the one end of the spectrum, we could just say approved, for all of these, as long as they're evaluated by multi-disciplinary team that gives people the most freedom.
Tony Yen	Yeah.
Jonathan Sham	However, certainly to me, it seems, why have a kind of policy at all if you're kind of just leaving it that open to interpretation. So again, I think that's more of a question, perhaps, for Judy or Gary, or you know someone from the agency side. Because, yeah, I guess I'm still not quite sure how detailed we wanna get. You know this, I I think to me this is like the minimum detail for me personally.
Tony Yen	Okay.
Jonathan Sham	But if, if we're looking for more prescriptive, we can certainly get way more prescriptive with each of these.
Judy Zerzan-Thul (HCA)	Oops. So handily, we have made these recommendations is something that we're comfortable with as a starting point, so that you, you can change it if you feel like it should be more perspective, you, you can do that, and we'd welcome your thoughts. But you don't have to get more prescriptive.
Gary Franklin (L&I)	Yes.

Judy Zerzan-Thul (HCA)	And thinking it like, what's the Goldilocks' sort of enough to be helpful, but not so that this is too hard to wade through. I don't know, Gary, did you wanna say something?
Gary Franklin (L&I)	I think just also wouldn't, isn't that the kind of stuff that the tumor board would do? The criteria that are there, the stage to Gleason, the PSA, etc. Isn't that the kind of thing they consider when they make a recommendation?
Jonathan Sham	Yes.
Gary Franklin (L&I)	So I'm not sure the agencies need to do that if the you know, that's the kind of thing that would be done?
Jonathan Sham	Yeah, I guess, yeah, that's well, I guess my question was, Hey, if that's the case, if it's certainly if it's that broad, you know, we can just say for all of these, you know certain, the 6 that we start off with that, it's approved as long as it's evaluated by multi-disciplinary team, I think you then run into issues of you do have a subset of patients who are not evaluated by multi-disciplinary team more commonly in the community and then how coverage is determining, determined in that subgroup. So I guess I'm a little resistant to giving up too much cause, you know, certainly, I trust the multi-d team at you know the Hutch, or Swedish or VM, or whatever large you know group, experienced group, but you do have a lot of patients who are just being treated out in the community without that multi-d and who don't have access to it so then you have, you know, an equity issue, issue at at play.
Tony Yen	Jonathan again, I apologize for kind of like putting you on the spot here. But if someone's gonna be referred to for SBRT when they almost invariably go through tumor board because that's not something that it's just kind of done in the community de novo I think?
Jonathan Sham	I don't have a list of all the plays, maybe, Simon, you can comment on the number of institutions offering SBRT. But it's more and more, it's not all at high volume centers.
Simon Lo	So I would say, at least for the end NCCN cancer centers being NCI sites. I think you know they all offer SBRT for various disease conditions. And for community centers, a lot of those have a long track record of offering this, you know, with a good outcome. So I think, yeah, unless you're working in a relatively small like center in rural area, typically, I think you know, in major metro, you know, come with practices, academic practices, they all have SBRT capabilities.
Janna Friedly	Right. I think the question is whether they have the tumor board, multi, the, is that the I think that was my understanding of the question.
Simon Lo	Yeah. So I would say, you know, for for sure, you know, for the NCI sites to, you know, there's always tumor board, and even for a lot of community centers, you know, they have tumor boards, but they may not be disease specific. It may be a general tumor board, but I think you know, typically, I think, yeah, you know, if

	they have discussed the case in in tumor board they'll need to document that in a chart and the in a medical record.
Jonathan Sham	I'll tell you right now, just knowing the practice patterns of many sites outside of the major academic centers, it is not necessarily standard to be evaluated by multi-disciplinary tumor board and to, as Dr. Lo mentioned, SBRT is not just offered at these high-volume sites, so this is something being given in the community. So I think, to rely on the tumor board to be that backstop, there's inherent risk in that.
Simon Lo	Well, I think at least multidisciplinary evaluation. So at least the patient record, the patient is seen by urologist and radiation oncologist, so at least there's documentation, because sometimes it may not be feasible. But there got to be a record that you know a patient is seen by both specialists. So multi-disciplinary discussion, at least. This is, you know, my take on it.
Jonathan Sham	Perhaps another way to look at it, you could turn on his head and say, Okay, well, when would you want a high GRADE, high risk patient to be treated by SBRT and I guess would the agency be willing to, you know, deal with those much smaller subgroup of patients on a medical necessity basis? You know, peer-to-peer kind of situation, you know, that's the other way to look at it is, you know, should we just put in the backstop and understand that there might be a really small subset of patients who, you know, fall outside these criteria, that it didn't potentially get treatment, if necessary, through other pathways. I guess that again, that's more of a, a question for the agency.
Janna Friedly	Well, I think that goes back to what our in our evaluation of the evidence is there evidence for this treatment for the high risk category and I think that's the, that's our, you know, sort of job here is to look at the evidence and use that to guide these.
Simon Lo	You know, I think one thing is even with the presence of evidence. But evidence may be similar to evidence may be similar, you know, between, you know, surgery, and you know, radiation, so there's an echo voice sometime. So I think multi-disciplinary evaluation, you know, in any event should be necessary.
Jonathan Sham	To answer your question, Janna, specifically based on the evidence presented us this is page 20-21 of the evidence review, so page 192, 193, of the PDF document, all of those has a ratios in the higher risk group.
Janna Friedly	Okay.
Jonathan Sham	Cross one have very low, low certainty. So I guess, to specifically answer the question, I would feel comfortable leaving those guardrails of risk profile in the policy statement.
Tony Yen	I agree with Jonathan. I just wanted to just kind of understand this whole thing a little better. So thank you guys for humoring me.

Janna Friedly	No, that's, that's important discussion. Okay. So I haven't heard any then specific recommendations to change the language that we have here. Just the group feel comfortable moving on?
Christoph Lee	So I would say that I favor just taking out the evaluation includes multi-disciplinary team analysis part, you know, for the maybe it is a minority of patients in rural settings that don't have a multidisciplinary team on board on site. But I think it puts a barrier in terms of access to care if they haven't established you know, very low, low, intermediate risk prostate cancer based on NCCN guidelines from their position, and they want SBRT, I don't know if I wanna put the barrier of having that individual go out and find a multi-disciplinary team to discuss the case before that could happen.
Janna Friedly	Well, I think the point that that I heard from Dr. Lo is that you know multi-disciplinary team would include the urologist, surgeon, and the radiation oncologist would, and that from a clinical perspective that is what you would at minimum would need, in order to proceed with this treatment in any case, so that would be a multi-disciplinary team analysis. Is that?
Simon Lo	Yeah, that includes just discussion doesn't have to be in the same spot or same clinic.
Christoph Lee	So progress notes would be enough?
Simon Lo	I think. So. Yeah, just documenting that, you know it was yeah, you had a patient who was showing, you know, evaluated by what was evaluated by urology and right on again you know, the decision is.
Christoph Lee	Yeah, so maybe clarify that it's just not a multi-disciplinary team analysis. But uh, evaluated it by multiple disciplines
Janna Friedly	And Josh, just for my clarification, the original 2012 decision was this the exact language that was used for the tumor board, or multi-disciplinary team?
Josh Morse (HCA)	Good question.
Janna Friedly	And I don't know if this is also addressed in other, just as reference and other, other existing policies.
Josh Morse (HCA)	Yeah. Are you seeing this now? Evaluation includes multi-disciplinary team analysis, eg. tumor Board, including surgical input, was how it was phrased in the 2012 decision.
Christoph Lee	Yeah, that's helpful just to have tumor board as one example. That's good clarification we could be consistent with this, I'm okay with that.
Janna Friedly	Yeah, I would think, unless there's a strong reason to alter it, I, I would recommend being consistent with the, the other coverage recommendation, for so that it's not confusing. Okay. Great.

Josh Morse (HCA) You're okay with, okay? And I'm, I'm gonna haven't traditionally done this. But I think it might be helpful to have some of this context here, just in the notes on this, and we'll figure out, maybe what to do with that.

Janna Friedly Okay, yeah, that would be great. Okay, so if we're okay moving on, then from prostate cancer, the next one is non-small cell lung cancer. And when we did our vote, I just wanna clarify the term that was used in our straw poll, though, was lung cancer was not specific to non-small cell lung cancer, and the agency recommendations for you know, non-coverage of small lung cancer and this I, so I do wanna make sure that we address this and we, we did hear some comments, I think it was from Dr. Kim about, about small cell lung cancer in particular. So again, I think we, we can start with non-small cell on cancer. But it would be helpful to address other lung cancer now as well. And, yeah. And then referring back to the 2012 coverage decision as well. So I just wanna make sure I understand the scope of this one, I guess, is the.

Josh Morse (HCA) So let me bring up the scope document.

Janna Friedly My apologies. I just wanna make sure that we're covering the scope of lung cancer that we need to address here. Did I confuse things?

Josh Morse (HCA) Well, I wonder if we can ask Beth for some about the scope.

Beth Shaw (CEbP) Yeah, yeah, we looked for the only studies we excluded for lung cancer were those where they were assessed as being medically, as being non-small cell lung cancer inoperable stage one. So anything that was currently covered we just did not look at. So we took any other evidence in any lung cancer that met any of those other inclusion criteria.

Josh Morse (HCA) So as I read the scope document, though it says, non non-small cell. There's a double negative in there.

Beth Shaw (CEbP) There is. So we were looking anything that wasn't a non-small cell lung cancer that was inoperable stage 1.

Josh Morse (HCA) Okay, so the policy suggestion is, is not a change or?

Beth Shaw (CEbP) That's your original one, isn't it?

Josh Morse (HCA) Gotcha right. So SBRT is covered for inoperable non-small cell lung cancer stage one. Okay, so this is not a change?

Beth Shaw (CEbP) Yes.

Josh Morse (HCA) It's there's some detail change, right? One stage, one and 2A versus previously it said stage one.

Beth Shaw (CEbP) Yes.

Janna Friedly	So, okay, so I just wanna be clear, though, because we did not reviews, specifically, stage, stage one is that was out of scope, so to make a decision here that includes that seems.
Josh Morse (HCA)	Did you? Did you look for the new evidence on this stage 2 you know, for non-stage one, or did you?
Beth Shaw (CEbP)	We certainly included any other type of lung cancer that was reported in the evidence that was not the stage one inoperable. So I'm just, yeah.
Josh Morse (HCA)	Okay, so apologize for the confusion, Janna. So what this would be, this would be, this would be, this is the original decision covered for stage one and the AMD suggestion is to add stage 2A. This is how the final would read, you know, taking from the old adding the new. Did I confuse that?
Jonathan Sham	The email comment on the selection of 2A versus just stage 2. In the current NCCN guidelines, both 2A and 2B are included in the recommendation for SBRT, and I'm just curious why 2A was selected here?
Janna Friedly	And we didn't review the evidence to that level of detail. That I can see.
Sophie Miller (HCA)	I think that was based on some one review of the evidence, and then 2 based on some of the other payer guidelines that we're covering 2A.
Janna Friedly	So again from our perspective, and looking at the evidence, I don't see how we could make that distinction based on what was presented. And I don't know what the clinical implications of that are either. So I don't know, Jonathan, you have.
Jonathan Sham	Yeah, I mean again, lung cancer is not my specialty, but, generally speaking, if you have node positive to see which is stage 3, you generally don't start with a local therapy like radiation. That's what the NCCN guidelines saying. So stage one and 2 that includes both 2 and 2 B, it is given as an option for node negative patience to start with radiation. So again, given we didn't review this level of specificity with the evidence, my instinct is to agree with the consensus guidelines through the NCCN. Again, it's a small change to just add 2B, or just don't comment on the stage at all. But again that, I think, would be consistent with the data we are reviewed and, and the national guidelines.
Janna Friedly	But just remove A so just stage one and stage 2. Okay, does anyone have any concerns about that?
Laurie Mischley	Nope.
Janna Friedly	Okay.
Josh Morse (HCA)	And that's it's a good, you know, part of the exercise that you will have to go through, when you finish this is considering the guidelines and differences. So you know, incorporating guideline thinking or guidelines that you feel are good is okay. They're in your report as part of the evidence base.

Janna Friedly Yeah, I think I just I, personally don't feel comfortable if we don't have the data to specify A versus B, and there's it's conflicting sort of guidelines or things it makes it very difficult to make that distinction with confidence for me. So okay, well, it sounds like we have wording on this unless anyone has anything else for non-small lung cancer. Okay, should we talk about small cell lung cancer now? This was right, it was recommended. So I think this was recommended to be on the list of not covered for treatment of primary tumor for small cell lung cancer. I didn't see data one way or the other to guide us, but there was, there were comments made about small cell lung cancer being included in in the discussion. So I just wanna make sure we're not neglecting, neglecting that.

Simon Lo So I don't know whether that would be helpful also society ASTRO, American Society for Radiation Oncology, has issued like a model policy, to payer model policy. This thing, you know the indications, you know, that are, you know, reasonable for consideration, I can send it through chat. It's online its a public information.

Jonathan Sham Simon, do you have any experience with treating small cell on cancer with SBRT.

Simon Lo Well, to be honest, I'm also lung cancer expert, It's just that haven't treated a lot since I've been at Fred Hutch, but in my experience, I think nearly 90% or more of the patients when they present, they present more advanced chest disease. So it's actually, even if you approve it, it's gonna be a small number of patients, 2% of the solitary, I mean a single, you know, tumor with all nodes or disease. So it's a rare situation. But in that situation I actually some patients may benefit from SBRT because they can be spared the toxicities of the chest. If you treat using external beam, you know there's much more radiation exposure to the lungs, and also the heart, but in most cases, actually, they have huge tumors, and nodule disease, most of them nearly is rare, it's a rare situation. Sometimes when you see a nodule, if I actually end up being a small cell and workup is negative, those patients get either go for surgery, followed by chemo or you know, radiation, and this case SBRT would be beneficial. But again, there's in a lot of data, because it's a rare situation. Most of them present with more advanced disease in a chest. They present with symptoms, most of them like, you know, SVC syndrome, like, you know, shortness of breath, you know, like chest pain, there's a lump in a super flat area. This is a rare situation rare occasion.

Sophie Miller (HCA) I just.

Josh Morse (HCA) There's a hand up, Janna.

Janna Friedly Oh, sorry. Go ahead. I was.

Sophie Miller (HCA) Yeah, this is Dr. Miller. I just wanted to jump in and make a quick comment about the ASTRO model policy for SBRT. That is a very, very broad policy that does not cite any evidence, and the evidence report does excellent job of citing the ASTRO recommendations that are guideline, based with a lot of evidence rather than the

model policy so I would urge the committee to not really take into account the model policy, because it is too broad and without evidence.

Janna Friedly Thank you. That's helpful context. And I am looking through the guidelines that were presented in the report for this, and trying to, it looks like it's really not addressed, and any of the guidelines that I can see other than maybe, although I can't tell the American Society of Clinical Oncology recommendation for patients with stage one or 2 node negative LS SCLC, which I'm assuming is small cell lung cancer,

Simon Lo The limited stage. Limited stage means non metastatic.

Janna Friedly Limited stage. Yeah, so that this is the only one that I can see that cover this who are medically inoperable, either SBRT or conventional fractionation is recommended. So that's the only one that I could see that address this specifically.

Jonathan Sham The NCCN also covers for the same criteria.

Simon Lo Okay.

Janna Friedly What's that?

Jonathan Sham The NCCN also covers for the same criteria you just mentioned, medically inoperable stage one and 2 of disease, so say they're consistent guideline recommendations.

Janna Friedly Okay.

Simon Lo So you know one, one way to address it is, me. It's just my thought, you know, in situations like this, you know, it has to be discussed you know, it's just like what you wrote, you know, multi-disciplinary team analysis with surgical and, you know, input, from medical oncology in this case, because small cell in general is like a medical oncology disease. That way you cover the bases because, you know, one cancer in most cases is always like a multi-disciplinary management for a small cell, and you know the medical oncologist doesn't think that it's a good idea, you know it won't be given. You know, one would have taken account, account patients, general condition, the situation, stage, well, you know they're addressing like stage one or stage 2 small cell staging system, basically, it's the same, you know we use AGCC. But in small surgery management-wise, I think we separate it's also into extensive station, limited stage, limited stage means, you know, it can be encompassed within the radiation. We still use that to categorize patients in clinical trials and also to guide management.

Jonathan Sham So Janna, back to your specific question, you know even though we didn't review this data specifically given that both ASCO and NCCN support the use of SBRT in the setting of this rare situation of stage one and two small cell lung cancer, I would be in favor of not specifically calling out that it's not covered in this list given

	and again, there is a possibility of data, but expert consensus is, it's reasonable in that situation. So again, I would not exclude it.
Janna Friedly	And this, I'm just looking at again in our comparator. I think Aetna also has the same, they include both non-small cell and small cell. Stage one, or stage 2.
Christoph Lee	Yeah, and this goes back to my general question to Josh and the HCA, do we have to? Since it's listed here, come out with a for or against statement. Can we just take it off the list?
Josh Morse (HCA)	I'm like, if you're asking me, I would say no, you know it was within the scope, Beth and team search for the evidence. It sounds like there's not a strong evidence base for this, but there is some community consensus about the use of this tool in these situations. So it's within your scope, and so it's there for you to answer, I guess.
Christoph Lee	Got it. So my take is that we have community consensus, we have guidelines, statements from societies, and that's the basis for evidence for a lot of these disease entities. Because our systematic review didn't find anything else. So that's the basis the expert opinion consensus. Can weigh that as sort of the majority evidence?
Janna Friedly	I think we it seems like individually, we, we can apply that as we see the evidence as committee members. Dr. Miller, did you.
Sophie Miller (HCA)	I just I had a point of clarification about the NCCN and guidelines for small cell on cancer. My read of the guidelines is that SBRT on emerging data suggests that SBRT is effective for patients with limited stage. So I think the guidelines are a little bit more nuanced from my read rather than yes, is a recommended treatment, rather the wording that I'm looking at in front of me is that emerging data suggests that it's effective just wanted to provide that clarification.
Janna Friedly	Great. Thank you. Yeah, I I think we're, I think we're clear that there isn't a strong existing evidence, but that there's, but there's some suggestions clinically, and I guess my question is, if we included small cell lung cancer in our coverage decision here above just included, that with the same criteria, are there unintended consequences that I'm not thinking of in terms of the scope of what this would be used for, and the implications for that. Is that too broad? If we just included the same criteria for both non-small cell and small cell? It sounds like it would, only it's a rare situation.
Simon Lo	It's very rare. Most of them have would have really, really advanced, you know disease in the chest, even if there's no distant met.
Janna Friedly	Okay.
Simon Lo	So I think you know I've treated lung cancer for like 15 years. I may have seen maybe 2 to 3 cases like that. Yeah.

Janna Friedly	Okay. Okay. That's helpful. So I with that, I would feel comfortable, adding that to we could either have it as a separate one with the same criteria, or add it to, to the I don't know if it matters from the agency perspective if we keep those separate or just, add that to the above, above one with the same criteria.
Christoph Lee	Can we just call lung cancer and not differentiate?
Sophie Miller (HCA)	Given they're clinically very different diseases, do we want to differentiate them now for the purposes of future review? Given how differently the pathology is.
Janna Friedly	If that would make it easier going forward, I think that would be fine. We could just have the exact same section, but just say small cell and take out the non but have it as a separate section. Is that with that, and then take out the and. Okay, in the parentheses.
Josh Morse (HCA)	So in the guidelines, you know, since are gonna play an important role here at all, as they are already are, summarized in the report, I think some of you are probably looking at that, but I think it's page 114. If you have that, those reports open on your multiple screens. Beth, do you have anything to add on that, or am I getting the page number right?
Beth Shaw (CEbP)	I think so. My only comment would be, I've just been trying to dig around in the evidence because they say moderate quality of evidence, but I can't easily find exactly what the basing that recommendation on from ASCO. But as you've said, they've gone through, you know the guideline consensus process, you know we assessed it as being a good methodological quality.
Janna Friedly	Okay. And then do it just as a kind of clarity. Do we need the NSCLC, the limited stage? Is that necessary here? Important to put in there or is small cell lung cancer enough? Given that we have this stage below. Does that matter?
Simon Lo	Stage one and 2 is implied as limited stage
Janna Friedly	Okay, we'll leave it, as is okay.
Laurie Mischley	Hmm, under small lung cancer. I think there's a non that has to be removed, second line, down.
Josh Morse (HCA)	Thank you.
Janna Friedly	Good. Catch. Okay. Great. Okay, let's move on to pancreatic.
Josh Morse (HCA)	Gonna take that off the list down here.
Jonathan Sham	So I'm happy to weigh in again. I guess I'm perhaps a bit, biased the wrong word, but I'm a bit more invest in this one, since I do this all day, every day, I think that we need a little bit more guidance. It's, this is by far the broadest policy statement of all of the disease sites, and I guess I'm not really sure why, it's kind of has the least kind of granularity. As far as the second bullet point of not covered with evidence is a direct invasion of bowel, stomach, that's really more of a safety

	profile that we're commenting on again. This is nothing about efficacy. Again, in none of the other groups do we kind of say you know, if it's by this structure, don't, don't treat. And so I guess I would be in favor of eliminating that. Given again we're leaving it to the discretion of the treating radiation oncologists to make those safety determinations. So that'd be my first statement. And as far as the actual indications for treatment, I think we need to add, just like we did in the other ones, the fact that if it's going to be first line, or I'll say if it's going to be in lieu of surgery. It needs to be, you know, deemed unresectable or deemed medically unfit, just like we did in the previous, I think, on lung, and again, almost all of these patients get chemotherapy first. You know, it's really hard, the, the only patient who would get radiation without chemotherapy would be those, since you can't tolerate it many. So I think we should be specific in that this is not a first line therapy that is kind of universal consensus guidelines data. So I just think a little more detail on this one.
Christoph Lee	Jonathan, what would you recommend for the second bullet point? There, medically inoperable. Do you want to ask me about chemotherapy as well?
Jonathan Sham	Yeah. So again, the second bullet point now or second circle bullet point I just I would remove. I would advocate removal just because we don't comment on it anywhere else, and but I defer to your guys thoughts on that. As far as when it's covered again, it would be covered as first line only in patients who are not candidates for chemotherapy, and that's, that's actually spelled out in the NCCN guidelines in black and white. It's only go to SBRT, if they can't get chemotherapy first, because chemotherapy is the treatment of choice. So SBRT in patients who are not candidates for induction chemotherapy is how it's worded there.
Josh Morse (HCA)	And if I'm getting the words wrong, please correct me. I'm not deleting I haven't. If there's consensus on deleting the second bullet point, just let me know.
Jonathan Sham	And then again, it is often used as consolidative therapy. So after patients get chemotherapy, and they don't respond, they're not, they're not candidates for surgery, then they would go to SBRT, and so I think the first bullet point could say locally advanced pancreatic adenocarcinoma after induction chemotherapy.
Janna Friedly	Mm-hmm.
Jonathan Sham	So that makes is very clear. So they got chemotherapy first, okay, you can get SBRT, and the second one is okay, you're not a candidate for chemotherapy because of some reason you can go straight to chemotherapy or straight to SBRT. I think that makes it clear, clearer that the order there's some guardrails in the order, so you don't have someone just going straight to SBRT without chemo cause that should not happen.
Josh Morse (HCA)	Is that, and I'm sorry. So I leave the induction here in this second dash.
Jonathan Sham	Yeah, yeah, and it would be it would be an or an or statement.

Josh Morse (HCA)	Oh, okay.
Jonathan Sham	So it's covered in the setting of locally advanced after induction, or they're not candidates for induction, so they can go straight to SBRT. I think that makes it pretty clear.
Josh Morse (HCA)	Is this an and?
Janna Friedly	And then.
Jonathan Sham	Sorry.
Janna Friedly	And inoperable.
Jonathan Sham	Yeah, and it's an and only to the second bullet. Well, I think it's fine the way it is.
Janna Friedly	So just to be clear. So they would have to be medically inoperable, or, you know, for whatever reason, and have already done chemotherapy.
Jonathan Sham	I think perhaps a way to loosen that would say, deemed not to be a surgical candidate, because that would include medically inoperable as well as surgically unresectable in a single group. Deemed, I think I would change medically inoperable to deem.
Janna Friedly	Yeah.
Jonathan Sham	to be a surgical candidate.
Janna Friedly	I, personally, I'm not a fan of the term, not a surgical candidate is. It's to me it's a little too vague, and as you very broadly in our field, in our, not on the situation, but just in general.
Jonathan Sham	If you wanted to be specific, you could say to have a surgically unresectable tumor. If you want to be very particular about the reason why, if you don't want to use that terminology, you could say tumor is deemed to be unresectable. Again that's another way to say it. Patient is medically inoperable or patient, deemed.
Janna Friedly	So do you need the medically inoperable as well?
Jonathan Sham	Yeah, I think it's the, It's the same as the second.
Janna Friedly	Yeah. Okay, so take that out. Tumor to be on unresectable or patient is deemed to high risk or declines operative intervention.
Jonathan Sham	Yeah.
Janna Friedly	Is that, and that's the same, I would assume that we had earlier, or we should, we should be consistent with our other language for lung cancer as well.
Josh Morse (HCA)	Here, this, so replace these statements with this.

Jonathan Sham	I think it's a little bit more all-encompassing in detail, you know, comments on the specific tumor characteristics as well as the patient level characteristics.
Christoph Lee	Josh, I'd be consistent with how you use and. I am above do the same thing below for pancreatic cancer. So we have.
Josh Morse (HCA)	Okay, I.
Christoph Lee	You see. Yep. how you have the quotes
Josh Morse (HCA)	Is that what you did? I get what you were saying?
Christoph Lee	SO you see how you have and capitalized after. Yeah, you're gonna do the same thing right? Right? There. Yeah. Okay.
Josh Morse (HCA)	I do. Okay, so you're suggesting, move this, just make this more obvious.
Christoph Lee	Yup, yup. So it's the 2 bullet points and one of the 2 bullet points, and then the tumor has to be unresectable as well.
Josh Morse (HCA)	Thank you.
Jonathan Sham	Then I might just, just the second bullet point, not candidates for induction, chemotherapy. It's just, it's referencing, I guess the tumor versus the patient, so you might just say, patient is not a candidate.
Janna Friedly	And then this non-covered for those with evidence of direct invasion of bowel or stomach. It sounds like the recommendation is to take that out. Does anyone feel strongly about keeping that in? I agree it feels like a, an unnecessary safety issue that the physician should be. It looks like Gary has a comment.
Josh Morse (HCA)	You're on mute. Gary.
Simon Lo	Okay.
Gary Franklin (L&I)	Now the ors and the ands are confusing. So you could have the first thing you can get it locally advanced. Is that right?
Jonathan Sham	Correct. After induction chemotherapy.
Gary Franklin (L&I)	Yeah, and then, or if you're not a candidate for induction chemotherapy and the tumor deemed unresectable, those two things go together. That right?
Jonathan Sham	That's correct. So.
Gary Franklin (L&I)	So I would separate those just a little bit to make sure that it's 1 point, and then it's a second point. Locally advanced is the main first point, and the second point is both of the next 2 things. Just the ors and the ands are just kind of screwy.
Janna Friedly	So if you move the or to the left hand side, where the and is, would that? So it's locally advanced pancreatic adenocarcinoma after induction chemotherapy. Or is it also locally advanced pancreatic adenocarcinoma?

Jonathan Sham	Correct, I think, perhaps moving the induction, after induction, chemo and patients not a candidate as a subheading or subtext under locally advanced, I think that's the clearest way to do it, because you could have.
Janna Friedly	Locally advanced pancreatic adenocarcinoma. Next line.
Josh Morse (HCA)	Next line?
Janna Friedly	Yeah, so put after induction chemotherapy. Following line, put a.
Josh Morse (HCA)	Oh, I see. Okay.
Janna Friedly	Because the patient is not a candidate, applies to the locally advanced pancreatic adenocarcinoma as well.
Josh Morse (HCA)	Okay, so this is sub to that is that what you're saying? And this is also sub, and this is an or.
Janna Friedly	Oh.
Josh Morse (HCA)	Or?
Gary Franklin (L&I)	I see.
Janna Friedly	I think we may have just made this much more complicated.
Josh Morse (HCA)	Alright. Well, I can go back.
Janna Friedly	Jonathan, Jonathan, help us out here, you!
Jonathan Sham	Yeah, so. So I guess to be clear the, the after induction chemotherapy would be for locally advanced only, other stages should be included in, in the patients is not a candidate for induction chemo. So let's say they had a resectable borderline or locally advance, but for some reason they can't get chemo, so they're really elderly, frail, then we would still give SBRT and, and that's also an NCCN guideline. So I guess to be specific after induction chemo and the second and currently would, I think, just remove patients not a candidate for induction chemotherapy. Get rid of that for just a moment. Get rid of the or, linkup, linkup after induction chemo with the previous sentence and then as a second one, what you just copied, as a, as a separate kind of heading. Below all of that.
Josh Morse (HCA)	Below all of it. After the end.
Jonathan Sham	All of that, I think all of it. Yeah, correct.
Josh Morse (HCA)	So above this tumor deemed unresectable, or.
Jonathan Sham	Below that, below that, as a as a new heading. Yeah, but it but it's not part of the, and it's it's its own.
Josh Morse (HCA)	So on. Separate bullet.

Jonathan Sham	It can. Okay? And yeah, can. And is there someone a designate?
Janna Friedly	Yeah.
Jonathan Sham	And is only to the tumor, is deemed sentence and can you designate that somehow?
Josh Morse (HCA)	I don't know why that's the same. So what do we put? What's the language that you wanna put in here?
Jonathan Sham	So that was.
Janna Friedly	A patient, patient is not a candidate for.
Jonathan Sham	Correct, so I mean, I think the easier thing about it is stage, and then candidacy. And so for locally advance you get induction chemo. So I get what I'm showing was that applies to both locally advanced and non-locally advanced patients. So you can list it under there and have a separate subheading for other. Okay. Yes. Well again, that's following up on SBRT is covered benefit for. I think the clearest way to do this would just be to divide it by stage, just so you did the other, we set stage 1, 2 before. So you list out locally advanced pancreas cancer after induction chemotherapy. And then second, in a second maybe second bullet point below that is you could list the other stages. So resectable, borderline resectable.
Josh Morse (HCA)	So that would be.
Jonathan Sham	So those would also be appropriate if the patient is not a candidate, if the patient's not a candidate for chemotherapy. So any stage non metastatic, if they're not a candidate. And then also, after induction chemotherapy for locally advanced, it seems to be unresectable like that, says the 2 big categories. How you divided here, like, I think to me stage is the simplest way to do it. But.
Janna Friedly:	I have to admit you've lost me here.
Jonathan Sham	How about this? How about I? Maybe I can.
Janna Friedly	Do you? Why don't you? Why don't you write it down? And then and then include in the chat. So we I think that would be easier.
Josh Morse (HCA)	Yeah.
Jonathan Sham	Yeah, that'll be. That'll be easy.
Josh Morse (HCA)	Why do I, I can email this to you, and you can actually, I can't do that.
Jonathan Sham	No worries.
Josh Morse (HCA)	Yeah, put it in chat.
Janna Friedly	Okay. Why don't? Why don't we, while we're doing that?
Jonathan Sham	No worries.

Janna Friedly	Why don't we given that the time? Why don't we move on to the next one? I think we're close with that one. It sounds like it's just some words missing. So.
Josh Morse (HCA)	Yeah, I think it's just formatting, if I understand right, in a period or 2 could solve it. But it is hard to do this way.
Janna Friedly	Okay, so oligometastatic disease. So this we also we're in agreement about cover with conditions. I think we heard quite a bit today about five you know the concern about restricting 3 or fewer lesions versus 5. And, and then you know, I, what I struggle with is also this third criteria of the performance score, and the ECOG score, because the way the data was presented, it was a little hard to link that to to the data.
Simon Lo	I think the size limit actually is a concern, because, as I've indicated before, you know, in those clinic trials in the R2G trial, the median tumors, like 8 cm. Most of them you don't see 6. Yeah, basically, excluding a majority of the patients.
Janna Friedly	So I think we're talking about the criteria. We don't have size here in the oligometastatic
Simon Lo	Oh, okay. Yeah.
Janna Friedly	Disease. I don't. I think that was for the hepatocellular.
Simon Lo	Yeah, yeah, so. So I think a based on the modern criteria 5. But you know not modern 3 lesions in any single organ. Is it very real that limit basically all the modern trials are using that 3 is actually in the olden days, that's you know, they use 3.
Clint Daniels	Josh, can you scroll down to show the oligometastatic in?
Josh Morse (HCA)	Yeah. Apologies.
Simon Lo	And also metachronous setting. There's also a significant role in SBRT for oligomets, so I think we shouldn't be just confining it to synchronous. And actually, those patients are metachronous. They tend to live longer with, directed to local therapy compared to synchronous ones.
Jonathan Sham	Simon, can you comment on the inclusion of your thoughts on the inclusion of multiple disease types in this oligometastatic basket. You know, breast cancer, hepatobiliary of the scope of cancer is, they're so different, the data is so different with all of them. What are your thoughts on bunching them altogether in an oligometastatic policy?
Simon Lo	Yeah. So I think the trial of the biggest impact is the SABER Comet, included everything. But again, you know, when you look at it, everything doesn't include, you know, the histology you mentioned about mostly a prostate, breast, lung. Those are the most common sites, sometimes its really hard to weed out situations, it's like, it's like metastatic, sometimes there's a role, but again, there's just not much data. So the sites with most data would be prostate, lung, and you

know even the renal cell, and but actually for breasts, you know, I think it's a more controversial, because I think one of the studies on oligo progression from Memorials Cancer Kennedy Center show that breast patients. You know, the survival was not different. But again, that was a very unique scenario. It's not first presentation, oligometast, what they call oligo progression. That means, you know, just isolated progression and limited number of sites. So it's a special situation of oligometasteses, and when you look at a definition of oligometasteses actually, the European group of EASTRO, they publish the guidelines, you know, how to define, oligometastatic disease. And actually, when you look at it, you pulling your hair out. Yeah, like, more than 10 entities and actually reviewed it that paper published in Lancet Oncology. So I think we need to actually put it in more broad terms. Because if you are too restrictive sometimes that can actually restrict access of this beneficial treatment to a lot of patients, because you just can't list out every single scenario, there's so many different types of histologies. But you know, sometimes, like patients, with like younger adults, they got like pediatric type, like disease, like pediatric type disease and they got oligomets, there's really not much information in like specific to that particular type of histology.

Janna Friedly So. So it sounds like having this, as its own category, is also consistent with, with other coverage policies and guidelines. And so I think it makes sense to do that. I just wanna point out a couple of things that are in other coverage. Other coverage guidelines. So the 5 or few, a fewer metastatic lesions rather than 3, and then and it's sounds like the in synchronous setting may not be necessary, so just 5 or fewer metastatic lesions, no more than metastasis, are limited, or no more than 3 metastatic lesions in one organ and then some coverage guidelines, like Regence, that is, in our report also has the primary tumor is controlled, stable or expectation of the same. It looks like United also has controlled primary tumor with no progression at the primary site. And then one other consideration is, and I'd be curious to hear what people I think is about life expectancy. There are some coverage guidelines that do say, if your life expectancy is at least 6 months as a criteria, so I don't know if that's something that we haven't discussed before in any context. But that is in other coverage guidelines.

Jonathan Sham I think, including a life expectancy by line is consistent with kind of the spirit of when SBRT is given. If you have a patient who would qualify for hospice, generally speaking, unless you're palliating a specific symptom, the treatment oligometastatic disease and really not undertaken, if life expectancy is less than 6 months, so I would agree with including that.

Janna Friedly And is that, is that true just for this category, or is that something that should be included in each of them. I haven't seen that in other categories, in other.

Jonathan Sham Yeah, yeah, it's because the low, the estimate survival in localized disease is all greater than 6 months for any, any of these diseases.

Janna Friedly Okay, so it only applies to this one really, by definition.

Jonathan Sham	So it's kind of understood. Yeah, even in pancreatic. Correct.
Janna Friedly	Okay. What does the committee think of this?
Tony Yen	It looks reasonable.
Janna Friedly	And, and I would probably say, it's yeah, or is it?
Josh Morse (HCA)	Trying to get the spelling right.
Janna Friedly	Yeah, there, we go.
Simon Lo	So how about the synchronous versus metachronous setting? Because actually metachronous patients, they tend to actually benefit from metastatic directed therapy then it synchronous patients. So I think it may not be a good thing to exclude an metachronous as patient.
Josh Morse (HCA)	I put in brackets, Janna, where you were, like, is it? You can choose 3 or 5 you can choose to delete the in synchronous. You can choose to add the controlled, just indicating the changes from the original little trying to a little bit.
Janna Friedly	Yeah, I, I have to say I don't. I don't know how to evaluate the in synchronous setting, so I would need to guidance on that, and what the implications are so.
Simon Lo	So I think metachronous setting typically it's like when the initial disease is controlled and then there's a new onset of metastatic disease, and many a time some patients can even avoid the systemic therapy if it's like limited mets treated with surgery or SBRT, can delay chemo or systemic therapy for some of those patients. And for synchronous, everybody would need to get systemic therapy.
Jonathan Sham	So, generally speaking, like, for example colon cancer, just as an example if you have metastases that occur within one year of your diagnosis of the primary that's considered synchronous, anything after one year is metachronous. Generally speaking, synchronous disease, on the whole, is considered more aggressive right because you have upfront metastatic disease versus diseases that slowly progressing and a year later you have a metastasis and so again, just oncologically generally speaking, local therapies like radiation or surgery we tend to use more from metachronous disease given the biology is more favorable, you know that you're less likely to quote unquote meta out after these local therapies. So I think that's why there's that call out in synchronous versus metachronous for this specific subgroup.
Simon Lo	And actually just using colorectal cancer as an example those patients with limited match in the lungs and liver about one quarter of the patients can have long-term survival in a 10 years.
Janna Friedly	So Jonathan is, is your recommendation or thought probably thought process about this to keep the in synchronous setting language then?

Jonathan Sham I guess, I just to be completely transparent, I still really struggle with this kind of grouping, because, you know, synchronous breast cancer is not the same as synchronous biliary tract cancer. Again, I think I just I'm not sure how to say this. I, I personally just wouldn't have them all together, if you're going to have if you're gonna have this group of all of these together, I think the easiest thing to would be just to defer the tumor board, because I'll tell you, no one would synchronous with 5 metastatic disease like tumors from the biliary tract cancer is gonna get SBRT. I mean that just that's not happening. I see Simon, nodding his head.

Simon Lo Yeah, like pancreatic, no way on earth.

Jonathan Sham Yeah, like that's just not happening. So it's hard for me to include that in this along with, you know, I can't remember all the other ones breast, adrenal, etc. Just because it's so that the practices are so dissipate across disease sites. So.

Simon Lo So I would say, you know, must include multi-disciplinary evaluation. I think that's the key is boils down to the group decision.

Janna Friedly Yeah. So we, so we have that at the bottom, as an and with these other things.

Simon Lo And yeah, I think must be documented and you know, to be honest, I think you know, we really do not want to just limited to synchronous, as Jonathan mentioned in some situations. Actually metachronous patients, they benefit much more from metastases direct to local therapy. You know, be it in a surgery or SBRT or RFA.

Janna Friedly Okay, yeah, so it sounds like, so it sounds like, there's a couple of options here. One is to keep this as a broad category without specifying the specific cancer type and then you would have to make this broader in order to be applicable for multiple different types of cancers, in which case we would need to take out the synchronous setting. I think if we were going to specify for each different cancer type, that would be a much more in-depth process to go through each one to come up with criteria for each one, then what we have outlined here, and we would, we would, I would think that at that point we would need to have more time with a subgroup working on that particular topic. That's.

Jonathan Sham So I agreed. So, Jan, in that case I would just take out in the synchronous setting, because that is selecting for even a higher risk group. So we don't want to call them out specifically, we don't wanna omit metachronous patients because they're the ones who may benefit more from local therapy. So I'm personally comfortable with the 5 or fewer just let's be clear, 3 per organ is arbitrary, that that is what it is, I think, controlled primary tumor is important to have, because it's something we talked about a lot in our multi-disciplinary teams. And the other things I think are appropriate as well. So I would, like I said, I'm in favor if we're gonna leave it as a group to have these kind of lose control.

Christoph Lee So I have a question for Simon and Jonathan. I agree with the 5 or fewer metastatic lesions, but everything else, I'm a little worried about. I think the

	performance scores only show up in one payer guideline. That's what I feel like that's come from. I don't see it in the evidence, and then in terms of the control primary tumor and life expenses be greater than 6 months. Are we getting into the area of palliative care? And are we going to prevent the use of radiation for palliative care? And I worry about that because I do think there's I don't know if we actually looked at that in our review right? So I don't wanna put unnecessary barriers up, especially since we're talking about very different diseases where radiation therapy could be beneficial and empowering in care centers.
Simon Lo	I think you know, in palliative care settings one would not be using SBRT, one would you be using a more simplistic setup. And also in situations like this cover under the spine met is covered under the spine, right, so oligomets gotta be covered because spine patients, they got symptoms. They covered under separate category.
Christoph Lee	Got it. Okay. So there's a work around for bone. Okay.
Janna Friedly	Yeah, so I would, I would argue that to keep the life expectancy in there, I think the maximum of 3 per organ. I don't see, you know, that really came from our clinical discussion, and not from evidence that I can see, or from other policies, so the.
Simon Lo	Can I make a comment? Actually in this SABER Comet trial, this is exactly what they do, and main reason is for safety, because, as I mentioned before, if one is treating multiple lesions like more than 3, you know, when you're doing 3 separate plans or one plan covering all the 3 lesions when there's far away, they're, you know, like bridges of the low dose radiation, they can damage the organ. And that's the reason why I try to limit that. So limit the number to 3 lesions for safety issues, specifically, you know, a technical issue. So how safe it is to, you know, get radiation, 3 lesions, and like one organ. That's a key thing. I guess you know only 2 organs.
Janna Friedly	And ,and again I think the you know, this goes back to the question, though, of the limitation on having something close to a structure for safety reasons. So that that to me feels like if it's a safety issue, that is part of the clinical decision making of the of this, I'm not sure that covers decision on that makes sense to me.
Simon Lo	I think you know, because this is like the criteria used by so far you know the, I would say the best trial available so far, and I think there's isn’t any excessive toxicities. So I think this should be a good guideline, because we know that this approach is safe because it's shown in a clinic trial to be safe and it's randomized trial.
Jonathan Sham	I, I think Christoph does bring up a good point, though, that the performance score, I mean is that analogous to the bowel or stomach involvement? Is that a safety thing? I mean, do we do we need to be that prescription with, with the performance score for this subgroup when we're not in others? I guess. I guess I'm in agreement, Christoph. I don't think we necessarily do.

Simon Lo	I think life expectancy is more important.
Janna Friedly	Okay. So we, we have found that the table to remove the Karnofsky performance score. I know we are, we, that we have a lot to cover still, I'm not sure, Josh, that we're gonna be able to get through everything today. So we'll have to deal with that. But is there anyone else from the committee that has any concerns with removing the Karnofsky i score? Okay. Okay. So I think unless anybody has any other concerns with the language on this.
Josh Morse (HCA)	Oh, Janna, we have till 3 today. So.
Janna Friedly	Yeah, I know. We still have a lot to cover, though. So I just wanna, I wanna make sure we we're able to try to get through everything. Okay.
Josh Morse (HCA)	So we were leaving in the maximum 3 per organ Yeah, okay, thank you.
Janna Friedly	Okay, great. Alright. So let's move on to hepatocellular carcinoma. Okay, so I know we had heard arguments to remove the 5 or fewer lesions, and the 6 cm, or smaller as this was, you know, sort of arbitrary, I guess, and really the key thing is, you know what you know, how safe the procedure is rather than a very prescriptive in terms of the size and number of lesions.
Christoph Lee	It seems like, if you took away that, the numbers and the performance scores, you'd still have the barrier of having inoperable disease and multi-disciplinary team analysis. Seems like that would be the most flexible.
Clint Daniels	The performance scores is that mostly about prognosis like, would it make sense to add life expectancy in if we're gonna take those out kind of like we did in the last one?
Janna Friedly	That's my understanding. But I'll rely on our clinical experts to guide us. Is, is there a reason here that we would want to use those performance scores specifically versus using the same language that we did before with life expectancy?
Jonathan Sham	I don't see a good reason to keep it.
Josh Morse (HCA)	So delete the performance score?
Gary Franklin (L&I)	And Kaiser says Karnofsky performance scores more objective than life expectancy?
Jonathan Sham	They are objective. However, again, kind of like we're talking about with the pancreas criteria, we didn't know how, we didn't know how useful it would be to specify safety parameters on treatment implementation, cause that's really what this is about this, you know, a high or low performance score is not going to change the efficacy of the treatment it's just going to change the risk profile. And again, that I think in general it seems like the committee is leaning towards deferring to the treating physician to evaluate that risk profile and not spelling it out. That's what I would be in favor of certainly.

Simon Lo	I think also, you know whether to over radiation, to the liver I think you know this isn't not a good indication of like whether it's safe for the liver to get it. Like, you know, people usually use the CHILQ to quote score, determine, you know how risky it is, you know, degree of the services. But of course, there are techniques to, it's getting too technical, but the techniques to minimize the risk, even for the, you know, higher shelf use core patients and you know, using different dosing.
Josh Morse (HCA)	So Janna, is the proposal to replace this with life expectancy? Yeah. Thanks.
Janna Friedly	That's that.
Christoph Lee	Can I ask our clinical experts? For liver cancer, there was a lot of evidence presented, not just on unresectable HCC, but early stage HCC versus RFA and then as bridge therapy for those a waiting liver transplant, can you comment on, on those populations and what do you think of that?
Simon Lo	So I haven't delt with liver transplantation patients too much, but I think you know definitely and it's been done, you know at our center, for patients are waiting for transplant.
Jonathan Sham	Yeah, so as Dr. Apisarnthanarax mentioned, there are a couple of treatment modalities that can be used for bridging and just kind of review bridging as how you are treating the patient, you know, while they're on the list in anticipation of receiving an organ to kind of buy time, and as he mentioned, none of in the setting of bridging specifically with the outcome of like getting to transplant none of these have really been validated. However, we use radio frequency ablation surgery, intraarterial therapy, and SBRT. SBRT kind of being preferred for patients who are even higher operative risk. You know, surgeon say I don't wanna go in there and do a microwave ablation, or they have bad blood vessels so they can't do it into arterial therapy, then then they'll use an external beam approach. Again, this data wasn't reviewed, but at least it's the current modern practice to consider that in the setting of inoperable disease or a high risk surgical candidate, given the preliminary data is showing some efficacy and at least as good as the other modalities in the setting of bridging specifically. But again, it's hard to lay out a study for you to, to justify that.
Christoph Lee	Alright, thanks, so I'm assuming the way this is written right now, bridging candidates will be covered. Because presumably they'll have life expectancy greater 6 months, and.
Jonathan Sham	Yeah, it seems like in all of these the intent for treatment is not really specified right? Definitive therapy versus bridging versus palliative and so it seems like if we're gonna leave it open for the other ones, we should also leave it open for this one.
Simon Lo	So, Jonathan, what's your thought about the size limit?

Jonathan Sham	Yeah, I think 6 centimeters is from old data and the modern data would support treating larger lesions as Dr. A mentioned, I think median size in the most recent trial is, I think, 8 cm. And again, it's not about what you're treating, it's about what you're leaving behind. And so I would agree, I would I agree to remove it given modern data.
Simon Lo	And you know, the yeah the modern approach is to adjust, based on the estimated left behind good liver.
Janna Friedly	Apologies.
Josh Morse (HCA)	So are you leaving in the 5? Does this, what does this look like? Did I miss something, anyway? I think that's what I'm trying to ask.
Simon Lo	So then that's the question. If you have like a main tumor, but have a 6 satellite nodules close by, so is it 7 lesions or? You know, sometimes it's difficult to define.
Christoph Lee	I agree, especially if you're not talking about metastatic lesions, we're talking about within the liver, the burden of disease could be it's not, can't be defined by a number of lesions.
Simon Lo	So, yeah, we have seen the sets lesions before, and then, you know, do call that a separate lesion or the same lesion part of it. But you know, theoretically, it can be treated in one piece. Auto disease.
Christoph Lee	Yeah, I, I didn't see the evidence anything about number of lesions
Simon Lo	And once again the key is the multi-disciplinary team analysis, you know, I think if you want to do something crazy, the team will stop you from doing it.
Janna Friedly	So then, as, as I'm reading this, then if, if we eliminate the 5 or fewer lesions, I'm not sure what, what the conditions are exactly then, other than evaluation from a multi-disciplinary.
Simon Lo	Well, I think you just see a liver confined disease, HCC that means it's priming non metastatic.
Janna Friedly	So if if you know, if, if we put primary hepatocellular carcinoma with a life expectancy of greater than 6 months, and evaluation includes the multi-disciplinary team is that?
Simon Lo	I think it's reasonable.
Janna Friedly	That seems very broad. But we're peeling away all of these criteria. And I'm not, I'm struggling with the evidence to find any more specific criteria that could be applied, based on what we reviewed.
Simon Lo	Okay, let me take a look at the RTOG trial, because different trials, they have different eligibility.

Tony Yen	Hey, Janna, I would.
Janna Friedly	Yes, Tony.
Tony Yen	Actually agree with just, you know, basically saying, you know, for hepatocellular carcinoma that's confined to the liver with a multi-disciplinary review, because there is really no other data that we reviewed at least with a literature that was been provided with us that really describes this carefully, but it seems like Dr. Lo may be referring, or he probably is looking at other literature that he has knowledge about, which is great. And that's wonderful, but I think both literature that we're providing is highly limited.
Janna Friedly	Yeah, I agree.
Simon Lo	I know where it is coming from in the R2G2 trial actually did limit to 5 or less HCC's in the liver. So I think if you wanna keep it, I think it's fine, because I think, you know if those lesions are close by, you just treat it as satellite lesions, and treat it as one single lesions. But if there are multiple sites, then you know, then you start to count a number.
Jonathan Sham	I guess I would add that all of the in the inclusion criteria, at least my understanding for all of these studies is the absence of extra hepatic disease. So I think we should just add that in there it's a assumed when we talk about it. But we should spell it out that the apps.
Simon Lo	Yeah, liver confined disease.
Jonathan Sham	Yeah, either liver confined disease, with the absence of extra pac disease, should be, should be here.
Janna Friedly	So what would if you were to keep the 5 or fewer lesions, what could you, 5 or fewer lesions confined to the liver?
Simon Lo	Yeah. Liver, fine, yeah.
Jonathan Sham	Cause, that's not specific. It needs to be its own.
Janna Friedly	It's own thing? Okay.
Jonathan Sham	Yeah, I might do it above 5 or fewer lesions. Just cause we think about metastatic disease first, and then how many are in the liver? So like the patient, has liver only a disease liver confined disease, or the patient has the options of extra patic disease.
Janna Friedly	Liver confined disease, and 5 or fewer lesions.
Josh Morse (HCA)	Ands after the cider we can correct this later.
Janna Friedly	And then.
Josh Morse (HCA)	And this is a period right? One of these, these 3 factors, or, is that right?

Janna Friedly	I'm struggling, reconciling those. That's because unresectable inoperable disease not a candidate for liver transplant is a very broad. Is, that is, that truly the intent here?
Jonathan Sham	I don't think so. I thought maybe I missed it when that was added, we're talking about bridging therapy, and so.
Janna Friedly	Yeah, so is this not relevant, then this whole or statement?
Jonathan Sham	I would. I guess, yeah, in the context of multi-disciplinary review, I'd probably remove that because that's baked into the decision to go to SBRT, because a lot of these you could do surgery you could do, SBRT, and the data is kind of equivalent. Yeah, I would just make it simple as that and that way there are some guardrails now. We have, but ultimately we're just referring to the multi d group.
Janna Friedly	Okay.
Clint Daniels	When I look at the agency language, I think that, or was meant to be between the outcome measures and that language we just deleted, so I don't think it's meant to be an or between the rest.
Janna Friedly	Okay. Okay, that makes more sense. Thank you. Alright. I don't have that pulled up. Okay. Does this sound, does this look, as our committee okay with this language, then to move forward? Okay, great. So let's move on, then, to the other conditions. So I think again, we're gonna need to go through these one by one and there was not a consensus, I think, on, on some of these, and so.
Josh Morse (HCA)	Well, I think you voted, maybe Val can show the result, but I moved up to the top. I think the 3 where more than half voted in the covered with conditions. I think that was the case. So I think there's a line after bone, anyway. Val, do you have that?
Val Hamann (HCA)	Melanie may have that hold on. Yeah, Melanie's got that one.
Melanie Golob (HCA)	And you're just looking for the vote, Josh?
Janna Friedly	Yeah, so we wanted to know there were some that we had consensus about non coverage, and then others where we needed to.
Melanie Golob (HCA)	Hmm.
Janna Friedly	I think, decide about coverage versus non coverage. So I think those require some discussion.
Melanie Golob (HCA)	Okay, hopefully, you can see my screen.
Janna Friedly	Okay. Perfect. So, so the first one for renal, we had 4 cover with condition to non-cover. So I think we need to discuss, oh, we need to discuss each of these. But in particular renal, head and neck and adrenal, since there was a little bit less consensus here. Oh, and bone. Yeah, we need to discuss all that.

Josh Morse (HCA)	Right? So it looks like you renal and bone you had a majority who said, cover with conditions.
Janna Friedly	Yeah. And then the rest were a majority not covered. Why don't we start with renal and discuss that? And I think the what, what I and I can explain my rationale for, oh, go ahead, Tony.
Tony Yen	Yes. Yeah. So my rationale for saying not covered is that it's on page 209 of the PDF page 37 of the of the evidence report, or really kind of just summarizes a single study from the evidence that says that what SBRT was associated with significantly worse overall survival, then people treated with ablation or surgery, and that's my rationale for saying not covered.
Janna Friedly	Yeah, and I think so just to follow up on that. I think that the flip side of that was that for people can't get surgery, or there's no other option, that was what I heard from the clinical that may have.
Tony Yen	Oh.
Janna Friedly	So. So I think that while that evidence showed that there wasn't definitely, we were at least from this one study was not benefit compared to those for those people where there's they are medically frail or not able to have surgery that this would be the only option that did I understand that correctly?
Simon Lo	So that would be a huge bias, because those who could undergo surgery, they have a much better performance status much better, like general bodily function less combability. So it is not randomized control study, you know, actually it is subject to, you know, various bias, because those who got SBRT of those who have no other options, and those have, you know, poor renal function many a time cannot undergo any other treatment safely. I think you know that's the.
Tony Yen	So Dr. Lo, I'm curious, just even though SBRT, it seems like, you know, from all the data that we're, the evidence we're presented is quite safe. How does it help people, maybe you can help me understand, how does that help people whose performance status is such that surgery would be too high risk?
Simon Lo	Yeah, well, the thing is, for they may not die straight away, but when it's the tumors bigger than 4 cm, the risk for distant metastasis will be much higher untreated RCC. That’s the reason why, you know for tumor masses less than 4 cm they cause more renal of masses, the risk for distant masses is much lower so they can watch, but once it is gone beyond 4 cm, the risk for distant mets is high, and the patient can have, you know, horrible consequences from distant metasteses. And also when the tumor is bigger, it's very vascular tumor, you know, it can bleed into itself when it becomes large. And they can actually continue to worsen the renal function, because, you know, when it grows, it would erode the kidney, the more kidney tissue will be replaced by tumor. That's reason why, you know, for small tumors for medically unfit patients we can watch, once it’s gone beyond 4 cm, and once the growth rate has increased, I think one would need to do some

	form of treatment. Many a time for RFA the tumor, in order for it to be effective, it has to be small that 3 Cm. If you want to do RFA, because it's just that heat doesn't periphery of the tumor, and when a tumor is close to the high level 2 issues, number one is heating effect, that means heat would be you know brought away bye the veins, because you know there's blood vessels right next to the tumor, heating back. Number 2 it can damage to ureter and the blood vessels the radiation, I mean the RFA. Because they're basically in a heating the tumor. So yeah, that's the benefit, because you know, for tumors smaller than 4 cm, for medically not approval patients, we typically do not routinely treat unless the patient is very inclined to do it because it risk for distant mets is low but once it has gone beyond 4 Cm you know, the risk for distant metastases increase.
Janna Friedly	Dr. Miller, you have a question or comment?
Sophie Miller (HCA)	I just wanted to make a quick comment and I appreciate the discussion about the some of the risks. But I think I encourage a committee to look at the evidence report and the study with 90,000 individuals which indicated that patients that underwent SBRT were actually worse off for overall survival as that, Dr. Yen pointed out. Thank you.
Simon Lo	Yeah, I think the main issue is, is this big selection bias.
Janna Friedly	Yeah, this was not a, it would need to recognize, it was not a randomized trial.
Beth Shaw (CEbP)	And it was only in people with stage one renal cell carcinoma.
Janna Friedly	Okay, thank you for that. Okay, so should we, I think because there was not consensus initially and we've had some discussion, I think it may be worth redoing the poll to see where we stand with covered with conditions or not covered for this condition. Would, are we able to to do that?
Val Hamann (HCA)	Yes. Okay, are you ready?
Janna Friedly	There any other committee discussion? Anything else? Okay?
Christoph Lee	I just noticed on the list of not covered in by the agency preliminary draft, a biliary tract cancer was listed, and we didn't really vote on that. And so I guess you know, if I'm looking at the slides this page 235, or 310. I was looking for evidence of biliary tract cancer, and the only thing I'm seeing in the evidence report is that for biliary tract cancer, SBRT is conditionally recommended in specific situations. But it's listed right now, has not covered so I'm wondering if Beth or Dr. Miller could comment on that?
Sophie Miller (HCA)	Sure, I'll make a quick comment here, I think, as has been referenced a couple of times during this conversation. Unfortunately for some of the cancer types, there was a lack of available evidence and this is one of the cancer types where there was a lack of available evidence. So a conditional recommendation and a guideline was not sufficient to have us recommend, and unfortunately due to the scoping of

	this that would fall under a non-covered decision based on the lack of evidence overall. So that's where that recommendation came from. That makes sense?
Christoph Lee	Yeah. So you're saying on the slide 63, which is page 235 and 310 in our documents. That's just based on one guideline from some society?
Sophie Miller (HCA)	Yes, sorry. I, I'm gonna not be able to navigate real time. But yeah, not enough evidence, yes.
Christoph Lee	Okay, Beth, you presented that. So do you agree?
Beth Shaw (CEbP)	I agree with the rationale, you know, if it's a conditional recommendation and then we didn't find any evidence. I'm just trying to look up the exact details.
Janna Friedly	So, yeah, Christoph, is your recommendation that we add that to so that we should actually vote on that specifically because it's in?
Christoph Lee	Yeah, if we're gonna say that it's not covered, I think we should probably vote on it.
Janna Friedly	Yeah, and I think that's there are a couple that we're not on the list of our votes. Right. There was sorry, pulling up too many documents here. Well, let's can. Can we come back to that? And work through we were about to vote on the renal cell. But we'll come back to the biliary, we'll make sure to do that as well.
Val Hamann (HCA)	Okay, so are we ready to relaunch that?
Janna Friedly	Yes.
Val Hamann (HCA)	Ending the polls.
Janna Friedly	So that was helpful.
Josh Morse (HCA)	Yeah.
Janna Friedly	How did, we have 5 voting members, don't we?
Val Hamann (HCA)	We have 6.
Josh Morse (HCA)	6.
Janna Friedly	We have, we have.
Laurie Mischley	Okay, I would love to hear from the people who said cover with conditions, what condition they would propose?
Christoph Lee	So, yeah, I can start. I'd say that the conditions would be again multi-disciplinary team discussion, and that there are no other options for the patients, right, so non-surgical, so pretty similar to what we have honestly for HCC, other than a number of lesions.

Clint Daniels	This is Clint. I also did, covered with conditions, and I was thinking very similar, basically unable to tolerate any other treatment.
Janna Friedly	So, from a process standpoint, Josh, how do we, how do we address so a 50/50 split?
Josh Morse (HCA)	Well, I think you keep working towards the conclusion. I don't know, there's not really another option.
Jonathan Sham	Yeah, I guess just in further support of the multi-disciplinary evaluation, these broad categories don't really take into account, you know, patient specific factors and disease specific factors, you know, renal cell carcinoma is not renal cell carcinoma, is not renal cell carcinoma. You can have a patient who has an incident, all finding on a scan that in a month, you know, doubles in size versus you can have something that sticks around for 5 years and then slowly starts to grow, and those are just very different cancers with very different prognosis and expected responses to local therapy, and so I guess that's why I have a little bit of trouble just blanket, saying, no, given the understanding that there's just so much heterogeneity in each disease, each tumor.
Janna Friedly	I think, and we're I have struggled and I actually was one, I apologize for making you all go through this, but I changed from a cover to a non-coverage, because, because it's hard to come up with criteria that are evidenced based for coverage and based on the on the one available study that we have while it's not randomized, it is a large study, and it is early stage included an early stage cancer. So I'm having a hard time reconciling the evidence that's available, limited evidence that's available with, with a coverage decision.
Christoph Lee	Yeah, and I think we're in a quandary here because it was included right as one of the cancers to look at when there really is very limited evidence. So we're asked to make a coverage decision on something that the evidence space isn't there yet. But that kind of defaults to not covering something which could be detrimental to patients. So I you know, I wish we had not included it in our discussion and I feel that way about many of these cancers, because.
Janna Friedly	Yeah, I think it's the same category as, as the rest of the list.
Christoph Lee	Exactly. I mean, it's if we're defaulting to not covering, I think there's a problem with our process here.
Beth Shaw (CEbP)	And you know we didn't, we didn't list any cancers that we were looking for. We've just taken what the evidence for any cancer that met the other criterion. So we didn't specify what exactly we were looking for. In fact, we did the exact opposite. We said, we know we're not looking for back to the you know stage one non-small cell lung cancer, we're not looking for cancers of the spine. We do have one study that was in unresectable, intrahepatic cholangiocarcinoma, if that's what we're talking about, is, is that the same thing? Okay.

Jonathan Sham	That's a biliary tract cancer, not a renal cancer.
Beth Shaw (CEbP)	Okay. I was still back on the biliary tract question.
Clint Daniels	Josh was this in the 2012 report was this, was this, ruled on then and ruled a no?
Josh Morse (HCA)	It may have been. I don't know if this, what is the one study that is now available?
Clint Daniels	I mean, we, we don't have renal cell cancer in general.
Josh Morse (HCA)	Right? So it would have been, yeah, go ahead, Beth.
Beth Shaw (CEbP)	Oh, I, I'm just trying to find it, but there were no eligible studies in 2012. So again they cast the net wide, they looked for anything, and nothing met the inclusion criteria and since then we've got that one comparative or more non-comparative study.
Clint Daniels	So back then they did make a determination on it, based on no evidence, with the determination to be no coverage. Is that?
Beth Shaw (CEbP)	I think. Yeah, they said, there's no evidence, so we will not cover it.
Clint Daniels	Okay. So if we were to vote no coverage, we'd be consistent with what's current.
Tony Yen	So, so my perspective on this is that it's really important that these therapies demonstrate some degree of efficacy, right? Compared to either doing nothing or compared to current standards, and at least with what I'm seeing over here right now, I just don't see that and so sometimes I think we have very human urges to do something rather than doing quote unquote nothing, but sometimes, perhaps not doing something is voice, sometimes can be a better course of action over here and that's what I'm thinking about. If Covid has taught me anything, being a hospitalist is that sometimes doing something is not always the best thing to do, and really, actually, sometimes really looking at evidence as clearly as you can really, that's the proof, does this thing even work it? Apparently works in some settings, but not all tissue is the same, I think we all know this by now, too. So that's where I'm coming from in terms of saying not now, at least not now.
Simon Lo	Yeah, so I think in the analysis.
Judy Zerzan-Thul (HCA)	Yeah, and this is, I just wanna jump in for a minute here, I think. And Gary can provide more history because he's been with this committee longer. But I think it's exactly it, Tony, is that like as a kidney study shows people that got radiation did worse. And you know if you can have surgery surgeries the better thing, and I think we don't want to cause harm to people, and we also don't want to give people false hope that by doing something that they're gonna get better because some of these cancers are very bad, and they won't, or it could cause harm, and so I think that's really if why I think this committee has traditionally been more on the side of if there's not evidence that something works, then maybe we, we shouldn't be

	doing it, and we should be trying to get that evidence. I don't know. Gary, do you want to say anything?
Gary Franklin (L&I)	Yeah, I agree with that completely. And also again, we can, we can always cover it in in the realm of, of a clinical trial. You know, if somebody wants to do a trial, even if it's just a registe trial, if it's an IRB approved study, you know, we could participate in that. We want to learn more. But I wouldn't base a decision on just expert opinion.
Simon Lo	Actually, there are 4 trials being completed and actually, there's a big study, although, it's not a trial, is published in Lancet Oncology, with a 190 patient. So actually in terms of the advocacy and safety, you know, based on those studies those are actually high quality studies. They all published in top oncology journals.
Janna Friedly	I think those are not yeah, so I would just caution again that we have to base it based on what's included in the report. So, and that again, there may be trials that that will be published.
Simon Lo	They have been published already.
Beth Shaw (CEbP)	Well, if I'm thinking about the same trial, it was a non-comparative study.
Simon Lo	Oh, yeah, not comparative, yeah.
Beth Shaw (CEbP)	So, So we, we included it for harms, but we did not include it for effectiveness, because we aren't able to determine, you know what would have happened if there would have had another treatment.
Simon Lo	Well, the key issue is, those patients would not have been another treatment because they're not eligible for other types of therapy. Because those are relatively a frail patient who would have a no other options.
Beth Shaw (CEbP)	And many studies have included either historical controls. You know I've done those registry type studies so that was a key exclusion criteria from an effectiveness side that we applied across the board so not just, for you know, renal cancer. That was something that we agreed right at the outset a priority. So, yeah, there are some studies that do exactly what you say, Simon. But do not, did not meet our criteria for this review.
Clint Daniels	This is, I appreciate the all the extra discussion, and I'm changing my vote to no coverage.
Janna Friedly	So should we, Josh rerun the, the poll at this point, now that we've had another discussion, just to see if we've reached consensus.
Josh Morse (HCA)	Yeah, sure. Val, can you bring that poll back up?
Val Hamann (HCA)	Yes. Ending, poll.
Janna Friedly	Okay. So we now have consensus for noncoverage. Okay.

Josh Morse (HCA)	So Janna, sorry to interrupt. You know we're at 10 to 3. At this point we should probably do a time check, determine if you want to continue beyond 3, or if we want to look for a time, reset this meeting and continue.
Janna Friedly	And we yes, so I think first, it'll depend on if anyone has hard stops at 3 o'clock in that that will of the vote voting members, and that that would preclude us going forward. So does anybody have a hard stop or a strong preference? Tony does okay. So that I think, makes it necessary for us to, to continue at a later time, Josh.
Josh Morse (HCA)	Okay. It would be good to. Oh, sorry. Go ahead.
Janna Friedly	Oh, go ahead! I was gonna say, we, we can spend the next 10 min trying to do as much as possible.
Josh Morse (HCA)	It'd be good to wrap up the TMS question, which is, we left? We can we're prepared to do that right now. I, you know I don't know if we're at a good stopping point with.
Janna Friedly	I think so, can we? Can you just remind us, which do we have left to, how many do we have left to cover? We have about 5 or 6, I think?
Josh Morse (HCA)	So you just made this decision on renal. The only other one, I think, where you voted as a group in your original vote, or was bone. I think you have bone and then you have this 1, 2, 3, 4, 5, 6, 7, 8 other that you had more consensus initially on, not covering.
Janna Friedly	Yeah. Okay.
Christoph Lee	So Janna, I'd say, you know, based on the discussion we had for renal, and the clarifications. What we can base our decisions on, what do you think about just doing the for each one?
Janna Friedly	Another poll?
Christoph Lee	Because I think we will have consensus.
Janna Friedly	Yeah. Yeah, I I think that sounds good to me, actually, because we may be able to to do that.
Laurie Mischley	I agree.
Janna Friedly	Okay. Why don't we, why don't we go ahead with? We'll do, we'll just redo the polls starting with bone and, and then we'll, we'll do that just for 5 min, no more, and then we'll spend 5 min on the TMS.
Josh Morse (HCA)	Sounds good.
Janna Friedly	The 30 versus 36.
Jonathan Sham	And just heads up. I did throw the proposed cancer language in the chat.

Josh Morse (HCA)	Oh, thank you.
Val Hamann (HCA)	Ending the poll.
Janna Friedly	Okay. And then, so that was for bone not covered decision. And then for?
Val Hamann (HCA)	Head and neck. Is that what you wanted next? Head and neck?
Janna Friedly	Yes, yep. Just keep going down, the list.
Val Hamann (HCA)	Okay.
Janna Friedly	Okay, so 83% not covered. Okay.
Val Hamann (HCA)	We're waiting on one more vote.
Janna Friedly	Can we have everybody vote on this one?
Jonathan Sham	Sorry, Janna, I was talking to a muted microphone. Sorry, I should ask a quick question about the head and neck determination. So in the, the studies, included the data report, a lot of them were comparing SBRT to brachytherapy, showing kind of equivalence between the two. So I guess my only concern is, what if we have patients who don't have access to brachytherapy and SBRT is their only way to get treatment, equivalent treatment, oncologically like, do we want exclude those people in this decision? I feel like people understand that they're voting okay it's not superior to this standard, but again, I think that to consider what if people can't don't have access to the standard, it should they be, should they have access to this other therapy?
Janna Friedly	So what we can do, I think, given that we have such a short time period, and we are going to need to spend a little bit more time with the coverage decisions for the other ones, we can maybe put that one aside to discuss a little bit more. So I can talk with Josh about how we can do that one, if that one needs a little bit more discussion. But right now, as as it stands, there was a no coverage decision from the from the group. Okay, we have any other polls coming up?
Val Hamann (HCA)	I'm waiting on one more vote for it. No, just kidding. Did you want to vote on biliary tract at all?
Janna Friedly	Yeah, I think if that is on the list, then we need to also vote on that one as well.
Val Hamann (HCA)	Josh was that on the list?
Tony Yen	Janna, do we actually have to vote on that one, or like there was really no evidence for that right?
Janna Friedly	There was no evidence right, but it was on the list, I think, of the no coverage, so I think by we, by definition, we need to address it, I think.
Tony Yen	Okay.

Janna Friedly	Is that right?
Josh Morse (HCA)	Beth, did you find any evidence for? Was it? Did it come up in the report?
Beth Shaw (CEbP)	And so this is intrahepatic cholangiocarcinoma. Yeah, is that the same thing? So we have one study, it was a comparative, non-randomized study, and it was actually improved SBRT. SBRT was associated with improved survival compared with 10 conventional radiotherapy. Low, low certainty of evidence, and I believe there's some support for its use in resectable ICC from the guidelines.
Josh Morse (HCA)	So, yeah, you would want to include that cause, it was, there was something found in in the evidence base.
Val Hamann (HCA)	Well, I'm having an issue, because it will not allow me to launch. So, Josh, I don't know if you can, Josh or Melanie can pull open any of the polls, but.
Josh Morse (HCA	Well, or we can do a voice vote. We have.
Val Hamann (HCA)	Just kidding it. It's because I'm sharing sorry. Okay, here we go.
Josh Morse (HCA)	Okay.
Janna Friedly	So clearly, we have 3 min left. We, I think we are going to need to revisit that one. So I think we will need to have a follow-up session, but I think we did make some good progress. I think I would if we, we have 2 min left. I don't know if we, we can finish the TMS discussion, but maybe we can just at least start it with a there was the question about the 30 versus 36 sessions. And, Josh, you had something you wanted, or Melanie wanted to.
Josh Morse (HCA)	So we investigated this and just back to the comment, the commenter did not provide any evidence. That's one of the questions that the committee needs to ask when considering these, these comments, there was a pretty detailed discussion about 30 why, the level 30. And Dr. Burns. He was the expert at the time, described the differences between newer technology which requires less and older technology, which was anchored to a higher number, the number being 36, which is what the commentary referenced. So if there is anymore detail that you need, you did discuss this in great detail at your March meeting, and you weren't provided with evidence for why it should be different from what you decided in March.
Janna Friedly	Okay, with that, I'm comfortable, leaving it at 30 sessions. Does anybody from the group have a different opinion?
Laurie Mischley	This is Laurie. I think we should leave it at 30 also.
Janna Friedly	Everyone else. Okay, Christoph, Tony, Jonathan, Clint? Okay. It sounds like we are in agreement to leave it, as is.

Josh Morse (HCA)	Can we do a quick, final vote on this? And this is one if, Sheila, Sheila, you can vote on this as well.
Val Hamann (HCA)	Yeah.
Christoph Lee	Yeah, I think I have to abstain.
Val Hamann (HCA)	I believe we're waiting on one more.
Janna Friedly	Did we get all of the votes?
Val Hamann (HCA)	No, we're still waiting. We only have 5 votes.
Janna Friedly	Good, everybody.
Christoph Lee	Is still here.
Gary Franklin (L&I)	Did somebody go off.
Janna Friedly	Well.
Christoph Lee	I have to abstain from the group, but I think Sheila is about so.
Janna Friedly	Oh.
Christoph Lee	You should still have six.
Janna Friedly	Sheila, are you there? It must be Sheila, if she's not answering here. Okay. Josh.
Josh Morse (HCA)	We may need to revote. I think Dr. Rege, I have messaged. Yeah, she indicated earlier what her position was on this, but I think we'll need her to vote so.
Janna Friedly	That's true, she did. Yeah, she did actually say that, but she was okay with leaving it at 30. But we may need to do an official, should we should do we need to wait till the next meeting to do that.
Josh Morse (HCA)	Yeah, I think we're in that position here. I don't want to cut, make any shortcuts on any of these processes. This is the process is what keeps this together. It's super important that we follow what we've developed, you know, or we just create risk. So.
Janna Friedly	And just to clarify this poll does not include Sheila's. This one that just popped up?
Val Hamann (HCA)	Yes, I would assume.
Janna Friedly	Because you closed it with without hers. Okay, just wanted. Okay. Okay, great. So I. So, Josh, we can follow up to sort of wrap up what needs still needs to be. There's still a few loose ends that we will need to vote on and to and to clarify, and then come back to the, to the wording for the, the cover with conditions, and finalize those. So we, we will work on.
Josh Morse (HCA)	Yeah, I think, what you'll be seeing from us in the last 30 seconds here before we adjourn is a, a poll to find a convenient time, which I imagine will be a Friday here

	in the next few weeks, with if hopefully and not waiting until July. We'll see, though, if we can find that time for you all that works for everybody present. It'll be another public meeting. I think we'll need less time, and I can work with you, Janna, on the amount of time that you think might be necessary to carve out, so that we don't either cut ourselves too short or take too much of your precious time so.
Janna Friedly	Okay. Great. Well, thank you everybody for your for your patience today, and, and for all that we were able to accomplish today. So look to finalizing that in the next meeting.
Josh Morse (HCA)	Thank you very much.
Janna Friedly	Thank you, everybody.