Washington State Health Care Authority

Washington State Health Technology Clinical Committee Meeting

Stereotactic Body Radiation Therapy

June 23, 2023

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Josh Morse (HCA) Yeah, we talked about this on our team yesterday. I think there's one of 2 ways to do it. The first way is the way I think maybe you should contemplate doing it. You know you've got on your draft that you've worked up so far a group that are covered with conditions, and then you are also working on a group that are potentially not supported by evidence and not covered. And we were thinking maybe you would vote on those 2 groups separately, instead of doing individually on the decision. The final decision itself, it'll appear that way.

Janna Friedly Okay, that makes sense.

Josh Morse (HCA) And I, yeah, and I think doing individually, it won't make a difference if something comes up that needs to be rereviewed. But you could also ask the group if they're comfortable with that strategy. So I think we're, there we go, that's a quorum.

Janna Friedly Alright. Great. Well should we go ahead and get started then?

Josh Morse (HCA) Yeah, why don't we do that.

Janna Friedly Okay and do you have the agenda that you can pull up?

Josh Morse (HCA) Yes, I'll share that right now.

Janna Friedly Okay. Great, and Sheila, did you have any remarks today? Are you, that you wanted to start with, otherwise we'll just go ahead and get started.

Sheila Rege No, I just I'm not sharing it because of the conflict I previously disclosed

Janna Friedly Okay. Great. Well, thanks, thanks for being here. Okay. So I just wanted to welcome everybody and thank you for taking time this early on a Friday, Friday morning of summer, to finish our meeting from last time, so we made good progress last, at the last meeting reviewing the topic of stereotactic body rate radiation therapy, SBRT. But we weren't able to finalize all of our decisions and so that's, that's the main purpose for, for today is to finalize that. We also at the last meeting, had some previous business. There were comments about the draft decisions for trans, transcranial magnetic stimulation, and we had discussed it, but we hadn't done a final vote. So that's the main purpose for today's, for today's meeting. Josh, was there any logistics that you needed to, to talk about before we, we get started?

Josh Morse (HCA) And we're just gonna quickly go over the introductory sides, which are abbreviated. Hopefully, you're seeing this presentation. Yeah. So this is our June 23rd meeting, this is a follow up to the May 19th meeting. If you're seeing this,

obviously, you're in the webinar, and we are recording the webinar as we typically do transcripts are available afterwards on the website. Reminder to please state your name and use your microphone. So as we just discussed, we're gonna go over the previous meeting business, the minutes, excuse me, the transcript from the last meeting is available, we don't approve that we'll approve the minutes, we'll do it quick recap on where we left off with the draft findings from the last meeting, but then move into the committee discussion and decision for SBRT to wrap that up. The other business we need to conclude is a final vote on the TMS draft decisions, draft decision from the March meeting, and there was discussion at the last meeting about a question, a comment there we can quickly revisit that and deal with that. So our goals, obviously to work to complete to the extent possible the work from the previous meeting. We haven't until 9 a.m. this morning. Again, we'll work on that SBRT, we'll finalize TMS. And so the draft determination for SBRT will be available, of course, for a 2 week comment period between now, and we hope the July 21st meeting, and that's our, our quick intro. Any questions before we move to the minutes? Okay, Val or Melanie, are you ready for a preview of the minutes? And then of vote?

Val Hamann (HCA) Yeah, I can pull up the minutes. It's loading. Can I everybody see that?

Josh Morse (HCA) That is showing. Yup. I can see.

Janna Friedly Yes, thank you. And these are also available in, in the meeting materials as well. So we will need a motion to approve the minutes.

Christoph Lee I move to approve.

Janna Friedly And if you could state your name on your name.

Christoph Lee Yup! Sorry this Christoph Lee.

Janna Friedly Great. And then a second?

Sheila Rege Second, Sheila Rege.

Janna Friedly Great. Thank you. Any discussion or comments? Okay, and, and then, how are we doing votes, Josh, did you want to do these verbal? Did you want to do these with hand, hand raising?

Josh Morse (HCA) Yeah. Val may have a plan.

Val Hamann (HCA) Yeah, I have, I can launch that when you're ready.

Janna Friedly Yeah, I think we're ready for that.

Val Hamann (HCA) You should be seeing that on your screen. And remember, this is only for panelists or HTCC members. Looks like we have 7.

Josh Morse (HCA) 7 approve?

Val Hamann (HCA) Yes.

Josh Morse (HCA) Great! Thank you.

Janna Friedly Great. Okay, great. So, and I apologize, I didn't introduce myself before we got started. I'm Janna Friedly and the vice chair, and I'm chairing this this meeting today. And so I the, the next order of business is to sort of recap where we, where we left off at the last at the last meeting, and, and then to finalize, our finish our voting and discussion. So at the last meeting we had worked through a number of of different types of, of cancer, and had drafted language for coverage with conditions, for coverage, with conditions for localized prostate cancer, non-small cell lung cancer, small cell lung cancer, pancreatic adenocarcinoma, oligometastatic disease, hepato, hepatocellular carcinoma, and these, the draft language that we had come up with, for each of these is, is up on the screen. And

	then we had discussed, based on a lack of evidence that SBRT is not a covered benefit for the treatment of the primary tumor for, for bone, renal, head and neck cancer, adrenal, melanoma, biliary tract cancer, and Merkel cell. And then the 3 that are highlighted are those that we had not discussed at the previous meeting due to time. So, so today, we need to finish the discussion of, or the, the straw poll vote right, Josh, of the breast, ovarian, and, and. Oh, sorry I do have that?
Josh Morse (HCA)	Oh. Did it change?
Janna Friedly	Yeah, it did. Well, you have.
Josh Morse (HCA)	Different one on there?
Janna Friedly	Yeah, yeah, you have a different one on there and you have biliary and Merkel cell as well as breast, ovarian.
Josh Morse (HCA)	Yeah, I think, yeah. So the separation. Okay, so what you're seeing, I think now as I adjust to Zoom here, I think it's the biliary tract, Merkel cell, breast, ovarian, and cervical that need to be concluded.
Janna Friedly	Okay.
Josh Morse (HCA)	The highlights, the highlight, had to do with a note from Dr. Miller's slides, the AMDC, AMD slides, that these were addressed in the original decision from, I think 2012. No subsequent information was found that met criteria for the new report. That's why they're, that's why they were stared or highlighted here from her presentation. Does that make sense, Janna?
Janna Friedly	Yes. Yeah.
Josh Morse (HCA)	As confusing as that is.
Janna Friedly	No, no, thank you for reminding me. I had thought we had finished biliary tract, and Merkel cell, but you're right? Okay, okay, so, so why don't we go ahead with the straw poll voting for biliary tract cancer. Oh, and there we go, and we have it up on the on the screen there.
Sophie C Miller (HCA)	Dr. Sham did you have a question?
Jonathan G Sham	Thanks, Jonathan Sham, Fred Hutch Cancer Center. I think if I recall correctly, we didn't formally vote on the pancreas cancer guidelines. I had submitted some proposed language, I think we got kind of hung up if I recall correctly, I posed some language, and then I don't think we had time to get back to it at the last meeting, so just wanted to bring that up as another order of business, as well.
Josh Morse (HCA)	Yeah, I could. So the draft that you see here has been reformatted, and Val took your, so your language, and tempted to incorporate it here. So I think our suggestion is that and there should be enough time once. This is concluded to go back, and then just go through and make sure that the intent for what's above before you do a final vote on the whole thing. If that makes sense to the committee?
Jonathan G Sham	Sounds good. Yeah, I just wanna make sure that we left it kind of an earlier state than the other ones. I just wanted to make sure it was addressed appropriately. Thanks.
Josh Morse (HCA)	Great. Thank you.
Val Hamann (HCA)	And we currently have 5 votes. Which that may be all we are. And now we have 6. I believe that should be all correct? Because Sheila's not voting so.
Josh Morse (HCA)	Yeah, Dr. Rege is not voting, but we do have a quorum, and 6, I think, should be the, the volume.

Janna Friedly Okay, so 67% not covered 33% covered with conditions. Okay. And then, did we? Okay. We missed Merkle cell.

Val Hamann (HCA) Okay.

Janna Friedly But so this, so we can do breasts. But we don't wanna, I wanna make sure we, we go back to Merkel cell. So we'll this one is for breast. And 83% not covered 17% covered conditions. Okay.

Val Hamann (HCA) And then here's that Merkle cell one.

Janna Friedly Okay, and we'll finish these and then and then if there are, if there's additional discussion just to, to finish up. Ovarian.

Val Hamann (HCA) Waiting on one more. There we go.

Janna Friedly Okay, so 83% not covered 17% covered. And then cervical cancer. And this is 67% and 37%, 33% covered with conditions. Okay. So, so that the majority have voted for not covered, but I did want to give an opportunity to discuss before we circle back to the to the previous decisions. If there's any, any further discussion that anyone on the on the committee would like to have about those given that there was not a unanimous decision about that.

Josh Morse (HCA) Looks like Dr. Sham has his hand up.

Janna Friedly Oh, thank you!

Jonathan G Sham Sorry, neglected to put it down prior to my last question. Sorry.

Janna Friedly Okay. Okay. Well, there's no further discussion about those then, then let's go back up to, to the previous decision. So at this point, what we, so we had discussed each of these last time had done a, an initial, and for coverage with conditions, and then worked on the wording of, of each of these, and so now is the opportunity to go back and talk about any suggested changes or concerns with, with how we have worded these. So I think what, what we should do is just, just to make sure that we're going through each one just to, to start with prostate cancer and I'll just open it up if anyone has any comments or concerns about the, the, the wording of this, this decision. And Josh could, can you clarify your comment off to the side that clarifies means that minimum evaluated by your urologist surgeon and radiation oncologist noted in chart? Is that, is that part of the official language here? Or was this just a comment?

Josh Morse (HCA) This was a note from, from the committee. I'm not sure which individual last time. And I think it's up to the committee as to whether you want to have a note like this attached to, whether it be prostate, or any of the other, other required multidisciplinary team language, and if not, we can just delete this.

Jonathan G Sham Yeah, I guess my input would be, I guess, surgical input just seems a bit vague. That might be like you talk to your surgeon buddy, in the hallway. I think maybe, what my sense from the committee discussion was we wanted more of a formal evaluation at a multidisciplinary clinic ideally, but in the setting we didn't have one of formal consult. So I guess I would favor being a bit more specific with that language.

Janna Friedly And so with, so with that, we'd have to be specific for each one of these that we use that language. So we would need to modify this language, to reflect the appropriate surgical sub-specialty, or note evaluated by a surgeon, and radiation oncologist at minimum for each of those. Do you have a thought about? Or have.

Josh Morse (HCA) Or was that specific to the, the prostate? No?

Jonathan G Sham	No, I don't think so again. I think, for all of the at least the first 3 here we discussed, you know, multidisciplinary review as being a central, kind of in the decision-making process. So I guess I would favor including in all of them.
Janna Friedly	And so, would, would your recommendation be to, to include the specifics? So your logic, surgeon for the first one, or evaluated by an appropriate, an appropriate surgeon, or?
Jonathan G Sham	Yeah. Guess again, I don't think we need to be overly prescriptive in this and we could just say a surgeon, radiation oncologist and if you have a surgeon who deems himself to be, you know, appropriate for to evaluate a particular disease, I think we can trust that in this setting. So you know, that means we can also just use the same language for each one which makes it a bit cleaner and simple we don't have to see urologist surgeon, thoracic surgeon, etc. We can just say surgeon and radiation oncologist.
Josh Morse (HCA)	And so would that be added to each like as an add on to this sentence in each.
Jonathan G Sham	So I guess it includes a analysis tumor board. I think just take out with, with surgical input, I just say tumor board, team analysis with an evaluation by a surgeon and radiation oncologist.
Janna Friedly	And with at minimum an evaluation or with evaluation at minimum, by a surgeon and radiation oncologist, or.
Jonathan G Sham	Yeah, I mean, I guess I just know that I'm reading. I don't see I mean I presume medical oncology is also involved. I mean, we didn't really talk about that previously.
Sophie C Miller (HCA)	Did you see Dr. Rege's chat, appropriate surgical specialist and radiation oncologist?
Janna Friedly	Yeah, I like having a, a little bit more, I mean it, it's implied with surgeon. But, but appropriate surgical specialists, I think, would, would be generic enough for each of the conditions, but, but a little bit more directive.
Jonathan G Sham	I agree.
Josh Morse (HCA)	Is this language accurate?
Janna Friedly	Well, so I don't like having evaluation twice.
Josh Morse (HCA)	Oh!
Janna Friedly	So an evaluation includes multidisciplinary analysis, umm, with at minimum the appropriate, an appropriate surgical specialist and radiation oncologist, or and that wording is not quite right.
Jonathan G Sham	Is it including? It includes multidisciplinary team analysis, including appropriate social specialist and radiation oncologists.
Janna Friedly	Yeah, but that would do it.
Simon Lo	Well typically for prostate cancer you know the diagnosis issue is established by the urologist. So automatically they will be involved because they, do the biopsy.
Janna Friedly	Yeah. Yeah, so I think that makes this make sense. Then. Any other? Sheila, you still have your hand up, is that another question? Or or is that, or did you wanna?
Sheila Rege	That's left over. Sorry.
Janna Friedly	Okay.
Sheila Rege	Trying to unraise it here.
Janna Friedly	Any other suggestions or comments about the wording?
Christoph Lee	I'm just wondering if appropriate is too vague? Is. Like what is appropriate?

Janna Friedly	I know. I think it's an attempt to make sure that it is the surgical specialist appropriate for that particular diagnosis without being so prescriptive and you know, especially if it's lung cancer.
Jonathan G Sham	Yeah, I personally would not favor getting any more specific that. We don't wanna get into the business of, you know saying board certified, or, you know, a member of this side or the other. I think, in that community, if they're deemed to be the person to evaluate that, I think that should be sufficient.
Janna Friedly	May we?
Josh Morse (HCA)	Should I replace with this language in the other places throughout sorry.
Janna Friedly	Yeah, I think. And Christoph the other, you know, option is to just take out the term, take out the term appropriate.
Christoph Lee	Yeah, I think that would make more sense. I'm just worried that you know, it could go both ways right? They could deny coverage if they don't think the surgeons appropriate. But that's only surgeon available to in that area right? So I think the appropriate just is, I think, unnecessary.
Simon Lo	Yeah, because the person who did the biopsy actually automatically is the appropriate surgeon.
Jonathan G Sham	I'm totally fine with getting rid of appropriate.
Janna Friedly	Okay. Okay, why don't we do that? Okay and then we can change that, change that for each of those three. Okay, any other comments? So we, we talked about what's the first can, can you scroll up again, Josh?
Josh Morse (HCA)	Yeah. I'm sorry.
Janna Friedly	Sorry. Oh, that's okay. So we were started talking about prostate cancer. Any other, any other comments or?
Sophie C Miller (HCA)	Yeah, this can. Can I make a comment? This is Dr. Miller.
Janna Friedly	Sure.
Sophie C Miller (HCA)	I do have some concerns about the assumption that patients have all been seen by a surgeon. I think some patients have biopsies in by interventional radiology. And so I'd be worried about assuming that a patient has been evaluated by an appropriate surgeon, often with hospitalized patients, we get a biopsy with IR wherever the, the lesion is most accessible and that's not always surgery, so I think we should be a little careful with our wording.
Janna Friedly	And just to clarify Dr. Miller, the wording as we have it now, with including a surgical specialist and radiation oncologist, is that, does that address?
Sophie C Miller (HCA)	Yeah, I was just more addressing, I think Dr. Lo's comment that they should have already been invited by
Janna Friedly	Okay.
Simon Lo	Ya know for prostate cancer, the diagnosis is nearly always, you know, on an elective basis, because there's actually, unless it's like advanced prostate cancer. You know, those patients typically just came in for elevated PSA. And so none of them are sick at all. So it's very unlikely to be in inpatient first. They would go to the urologist first, after being detected to have elevated PSA.
Janna Friedly	Okay, well, so let's, so it sounds like, we're okay with the, the wording for the prostate cancer. Let's just review with the non-small cell lung cancer.
Simon Lo	Good.
Janna Friedly	And if there are any additional.

Simon Lo I think it's very appropriate. Although we didn't have the word appropriate there. But I think it's appropriate.

Janna Friedly Okay, and how about now moving on to small cell lung cancer? It's a similar. Just wanted to be sure. Okay, so let's move on then, if there's no additional comments or concerns to the pancreatic adenocarcinoma. Jonathan, do, do you wanna just summarize or bring back your, your concerns that you had last time? And the wording suggestions?

Jonathan G Sham Yeah. So the I think original proposed verbiage was quite broad. It just, it is allowed, or is covered, and there was really no guidance on when it was covered. I'm realizing, you know, now, in seeing it next to all of the other kind of recommendations that it's a bit more prescriptive. And perhaps we can talk about how we wanna structure this. But the current wording is essentially aimed to target patients who either cannot get chemotherapy or have unresectable disease or patients who have undergone chemotherapy, and then still haven't unresectable disease. Those are really the 2 times that SBRT is used routinely in the treatment of pancreas cancer. And I think, again, looking over this again, I think that this incorporates that, but I'm happy for any feedback from the group. So just go through it from, from the top, you essentially, you have localized disease, and you, you can't get chemo for whatever reason and you can't get surgery. Or you've got chemo with, that's the first kind of group, the second group is or you got chemotherapy and it's still deemed unresectable, or you're still deemed too high risk for surgery, or you don't want or the patient doesn't want surgery or essentially, they've locally advanced disease after induction chemotherapy. The last, the or I guess, including that last line in the or I guess isn't, it does make it a bit confusing. I'm not, I realize it's made to kind of mirror the other recommendations. Perhaps that could be at the very top?

Josh Morse (HCA) Move the third group here up to the top?

Jonathan G Sham Just the, the last.

Janna Friedly The last bullet?

Jonathan G Sham Yeah, and I guess I think this may be a kind of a duplicate. This last. Yes, so I guess the last essentially, very, very last bullet just needs to be, I think, moved up to the top and be its own thing. And then the I think the is a duplicate, the, the very, very last.

Josh Morse (HCA) This bullet here? Okay.

Jonathan G Sham Correct. The last 2 bullets at correct, and then the 2 bullets above that I think, are just duplicate. I don't think those are necessary.

Janna Friedly Yeah. So that so the evaluation, including, would apply to both of.

Jonathan G Sham Yeah, that's everybody.

Janna Friedly so it could either be included as a fourth bullet in each of the, the top or the top, or just at the very top, with and.

Jonathan G Sham Yeah, yeah. Or you could change the last or to and, that would also achieve exactly, exactly.

Josh Morse (HCA) And get rid of these 2 bullets? Okay, so these 2 go away. Is that what you're saying?

Jonathan G Sham Yeah, and.

Josh Morse (HCA) And then this is an and?

Janna Friedly Yeah.

Jonathan G Sham Yeah. I again, where are you placed?

Janna Friedly The and has to apply to either one of those first 2 conditions, though so.

Jonathan G Sham Yeah, you could move it to the top and push and yeah.

Janna Friedly Yeah, there we go.

Josh Morse (HCA) Something like that is the intent?

Janna Friedly Yes.

Christoph Lee Jonathan in your mind, could you at all combine the first 2 categories, because it seems like the differences, whether or not the patient had an induction chemotherapy, it's at least one of the following.

Jonathan G Sham Yeah, I mean you, essentially, you, you could save before or after induction chemotherapy. I guess, I guess in one setting that they're not a candidate for it, and therefore that's why you're doing SBRT. And the other one is chemotherapy didn't essentially the disease persists after chemotherapy and that's what you're doing as SBRT. That is, that really the 2 only reasons why you'd do it. If you have, if someone has idea for kind of better for clearer verbiage.

Janna Friedly You could, I think you could say nonmetastatic disease, and is either deemed not a candidate for induction chemotherapy, or has already undergone induction chemotherapy. And has at least, and yeah, and yeah, so that seems like that.

Jonathan G Sham I like it.

Janna Friedly Would work, and then you can get rid of the last 2 bullets, and then you could just, that would also eliminate the need for the and, and you could just put that as the fourth bullet.

Jonathan G Sham I like it cause it also aligns with our other recommendations, the other verbiage of the other disease sites.

Janna Friedly So, Josh, so the last bullet would be, I am, yeah, it's.

Josh Morse (HCA) That sub, or?

Janna Friedly Yeah. That would be under, under the operative intervention declined. Oh, no, at least one of the following. So you want this for all that. Never mind. So you do need an and to then.

Josh Morse (HCA) Well, okay.

Janna Friedly Yeah, so you do need that other and. Sorry, cause it's, it's at least one of the following.

Josh Morse (HCA) That's right.

Janna Friedly So, we would want that in any, in any of those.

Josh Morse (HCA) Something like that?

Janna Friedly Yeah. Okay.

Tony Yen I like that better.

Janna Friedly Okay, any other comments or thoughts about that? Okay. Great. Let's go on to oligometastatic disease.

Josh Morse (HCA) Yes, I need to correct that link.

Janna Friedly So, Josh, I would just recommend, so I don't like the all of the ands at the end of the of these, so could we, could we say, you know, oligometastatic disease when each of the following criteria are met, or something like that, if these are, these are all ands. Does that? And, Jonathan, yeah, your hand is up.

Jonathan G Sham Yeah, I just want to come. I think the first and third bullet points are a bit redundant, like appropriate imaging known and widespread metastatic disease well that is 5 or fewer metastatic lesions, so I think we can actually just get rid of

	the third bullet point altogether. For the sake of clarity. I can't imagine, like you can't have 3 with, and one.
Janna Friedly	Yeah. That makes sense. Okay.
Clint Daniels	It's per organ, though, so wasn't there concern that if they had widespread whole body but 3 in each organ, like, I think that's maybe why we had the third bullet.
Jonathan G Sham	But it's 5 or fewer total. So.
Clint Daniels	Gotcha. So that's the total number, that's not okay. Thank you.
Janna Friedly	So do we need to write the word total 5 or fewer total metastatic lesions ir is that understood the way it's written?
Tony Yen	I think that's already in the first bullet.
Jonathan G Sham	I heard.
Janna Friedly	Well, I mean any first bullet, do we need the word total? 5 or fewer total metastatic lesions? Or is that redundant not necessary?
Jonathan G Sham	I think it's a bit clearer, so I, I would favor adding it. I know we're trying to keep things short, but I think adding total makes it clear.
Janna Friedly	Okay. Any other thoughts or questions about that? Okay. And then hepatocellular carcinoma. So I would make the same recommendation about the ands since these are all, I, I would mirror the wording.
Simon Lo	So I have one comment going back to oligometastatic disease, I think there's some circumstances where the primary tumor is being managed together with the oligomets at the same time using radiation. So the control primary tumor, you know, it depends on what is synchronous or metachronous, you know the disease. Because sometimes, if it is synchronous the primary tumor may be treated together with the oligomets, and if we, you know, put control primary tumor, then we would exclude those groups, of those groups of patients.
Jonathan G Sham	I guess the question is, would you also, in the setting that where you're also treating the primary tumor, will we be using the guidelines for that specific tumor in addition to the oligometastatic guidelines, for example?
Simon Lo	Yeah, absolutely. But I think there are circumstances where sometimes we treat well, you know, for lung cancer, you know, many a time in the primary tumors treated along with the oligomets.
Jonathan G Sham	Correct, I'm saying so then, therefore, with the patient, then need, if you scroll up, need to meet the criteria under the non-small cell lung cancer guidelines for the primary, in addition to the oligometastatic disease.
Simon Lo	Yeah, because there are circumstances where, let's say for example if the patient is locally advanced disease, the patient would get the current for the concurrent chemo rets for lung cancer and then for the oligomets after the treatment many a times, sometimes they do radiation. And actually for prostate as well. Sometimes the primary tumor is treated along with the oligometastatic site, so if we have to mandate control primary tumor, those patients would become ineligible for coverage, which is actually not good, and you know there's a clinical trial, showing that you know, treating the oligometastatic sites along with the prostate, and patients with limited mets from prostate cancer may be beneficial. Yeah, I understand that SBRT is not used with concurrent chemo rets sometimes. What I'm saying is the primary tumor may be treated with chemo rets and then, you know, followed by SBRT alone without concurrent chemo, you know to the oligometastatic sites. So I think you know it's not suitable for every single disease

	site, but I think, in a way like put a mandate there that would exclude some of the patients.
Jonathan G Sham	So DR. Lo, is there data for adjuvant SBRT after chemo rads in the setting of metastatic prostate cancer to the primary?
Simon Lo	Actually, for prostate, they do not do concurrent, and I think the, there are multiple of prostate cancer trials, I would need to actually take a look, but I think you know, we have actually done that in practice. I think there are a lot of trials from Europe and from, the from, from the UK actually treating the primary site in oligometastatic disease. I'll need to, you know, take a look at the data in this trial. But you know, we just put a blanket statement there, those patients would have been excluded from coverage.
Jonathan G Sham	Maybe I could just ask Sheila, in your practice for any disease site, are you following whole course chemo radiation with SBRT to a particular primary site?
Sheila Rege	Well, usually we, I hope you can hear me, we look for low tumor burden and the SBRT dose is high, and not generally Dr. Lo, not generally given with concomitant chemotherapy.
Jonathan G Sham	No.
Simon Lo	No, never, basically, never. What I'm saying is sequential. But you know, in that setting the primary site, the thing is because when you determine the give SBRT, when you know before any treatment, you know, map out the plan. So, a new diagnosis, of course, the primary site is not controlled, so those patients would automatically be excluded from coverage SBRT after the treatment of the primary tumor.
Sheila Rege	Correct. And that's why control primary tumor.
Simon Lo	Not to the same site I'm talking to.
Sheila Rege	Because of the primary tumor, is not controlled with concomitant chemo radiation. We generally don't do SBRT. Just a general guideline.
Jonathan G Sham	Sheila, I think what he's saying, is the patient's gotten full course chemo RT, they've gotten 6 weeks chemo RT, and then they're following up with SBRT after to the same site. I guess my question.
Simon Lo	Not for the same site. I'm talking about the oligomets. Oligometastatic sites.
Jonathan G Sham	So, I guess. But your, my understanding was you were talking about how to treat the primary tumor in the setting of oligometastatic disease, correct?
Simon Lo	No, I think yes, so the requirement for control primary tumor, you know. It doesn't matter how you treat a primary tumor, it can be like surgery, or chemo rats but what I'm saying is if you plan on doing SBRT, you plan from the get go before the treatment of primary tumor, like a synchronous occurrence, synchronous oligomets.
Josh Morse (HCA)	Not an expert here we have a couple, we have our evidence folks here, and Dr. Miller's here. My impression of how this was crafted was that if it was non-small cell lung cancer that was for non-metastatic non-small lung cancer, and separately, if it was a metastatic, then it would we'd be looking at the policy, for oligometastatic is that how other people understand how the intent was here?
Jonathan G Sham	Yes.
Simon Lo	Okay, what? I'm, okay, it's fine.
Sophie C Miller (HCA)	Yes.

Jonathan G Sham Oh, so I guess, Dr. Lo, just again I,I wanna make sure that your concerns are addressed.

Simon Lo Well, the thing is there's circumstances where there's like synchronous occurrence of oligomets, as I said before.

Jonathan G Sham Yes.

Simon Lo So many a time when you plan a treatment, you plan if it's like the primary tumor and oligomets, you plan, you know how you treat, you treat a primary site first, and then the oligometastatic sites, sometimes not for all patient.

Jonathan G Sham So are you saying that in some patients you might be treating the oligomets first, and then the primary, and that's why you have concern?

Simon Lo No, through the primary first, and then oligomets.

Jonathan G Sham Okay.

Simon Lo So what I'm in that setting, if you put that statement, the primary site has to be control first, at diagnosis of course it is not controlled, because the patient has, you know, has no treatment yet.

Jonathan G Sham So, so you're, you're concerned about your planning imaging your concern about starting the evaluation of SBRT in prior to them. Having treatment for their primary. Is that right?

Simon Lo Yeah, so, but I think, of course you can. Maybe we can modify control of primary, in synchronous, in metachronous, you know, oligomets. So that way, so for those patients who got progression at the treatment of primary site, and then with oligomets, so I think because the primary side is not controlled is okay to, you know, require control of the primary tumor before we can consider treating the oligomets. But for synchronous ones, I think if we put a statement there that would, you know, put a roadblock to appropriate treatment.

Jonathan G Sham I understand, but to be clear, you're not.

Simon Lo Because oligomets they are synchronous and metachronous.

Jonathan G Sham I understand but to be clear, your concern. You're always treating the oligomets after the primary, but you're concerned about the pre-primary treatment planning like Sims.

Simon Lo Yeah, sometimes there are some patients, you know, who would, you know, get treatment to the primary first, and then treating the oligometastatic sites. Not all of them, but what I'm saying is, if we put a blanket statement there, they would, you know, block all those patients who would have been benefited from treatment of their oligomets from getting coverage. But for metachronous, I think it’s appropriate to say that you require the primary tumor to be controlled. I would say.

Jonathan G Sham I guess the way I.

Sheila Rege Dr. Lo, if, if I could ask if it is a synchronous presentation, you still treat the primary, and then the next decision is only if the primary is controlled, if the primary is not controlled generally SBRT is not done.

Simon Lo Well, I think sometimes if there's a salvage treatment of a primary tumor sometimes, you know, we will consider treatment of the oligomets with SBRT or surgery, or whatever, but I think you know, in that situation for savage treatment is only when you can remove the tumor you zap the tumor, tumor is control, then it's appropriate to treat the oligomets. But you know, I'm actually addressing the synchronous scenario, synchronous presentation.

Sheila Rege Right. So if the synchronous, your primary attention initially, is to control the primary tumor and make sure that's controlled prior to making a decision on the oligomet, even with a synchronous presentation.

Simon Lo Well, I think.

Sheila Rege And I think, that is, is that a rare situation that you're kind of trying to describe like, I worry about confusion.

Simon Lo Actually, I would say, okay. So actually, if we are treating the primary and oligomets, and you know, I mean, when we, when we begin to treat a patient, actually, it would take several months to know what it's controlled or not. And we seldom see patients progressing through radiation. So basically, it would take several months before we can determine whether the primary site is controlled. Even the oligometastatic sites are controlled after radiation. It takes months that, like surgery, you just whack it, and the tumor disappears.

Jonathan G Sham I think that by using this kind of vague language of controlled we can leave it to the discretion of the centers to know what that means. You know, at least at our center, you know we could treat with SBRT, or whatever modality and then that's considered controlled, and then they could then move forward with the oligometastatic treatment. You know you don't have to observe stability by resist criteria over 3 so we're not being that prescriptive in the guideline. So you know, if that center says okay, yeah, it's controlled because we treated it with either long course radiation or surgery or what have you, to me, I think the, the guidelines still give enough room for people to perceive with treatment of oligo, oligometastatic disease as is written.

Simon Lo Yeah, if we interpret that way, I think it's fine. Yeah, because sometimes when you put.

Janna Friedly There's no specificity in terms of, you know the definition of controlled here. So I, I think that covers that scenario. Okay, and any other comments or questions before, on any of these? I think the next, the next order is to finalize the votes, and I think, given that we have reviewed all of the conditions. That there's essentially 2 categories cover with conditions, and then and then a category of non-covered. I think that voting on all of the, the conditions covered with conditions, conditions in, in one vote, and then then non-covered conditions in one vote, make sense to me unless there's any objections to doing that. If anyone wants to do these individually, we can certainly do that.

Josh Morse (HCA) Before we moved to vote. Oh, is there a question? Jonathan, it looked like you had a question?

Jonathan G Sham Again, I may just a more general question about kind of how we approach the data, just as a group. For some of the diseases at the bottom of the list, I think it's in, in the data report, I think it was adrenal, and maybe biliary, I have to go back and look. But there was essentially equivalent efficacy with SBRT and you know other therapies, and I brought, brought this up briefly you know, when there was not, in a setting of non-superiority whether or not we are kind of globally speaking, recommending, not, not covering okay cause there's no superiority or out of concern for access, equity, and setting, you know, someone doesn't have access to the, you know, quote unquote equivalent treatment elsewhere. Whether or not the group would lean towards, towards covering that you know, in the setting of equivalent efficacy. Again that was just kind of only other outstanding data issue

that I, that I was hoping to bring up and just see if we had a general approach as a group to that scenario, because again, in a couple of these you know small ones at the end the data, the data report did mentioned equivalency.

Janna Friedly And specifically adrenal you mentioned. Was there another?

Jonathan G Sham Adrenal, biliary in the in the evidence report. And again, this may be kind of too broad a question that we can kind of take it on a case by case basis. But I know we kind of ran through these a lot. There was a lot of, there's no superiority, so don't cover it. I just wanna make sure we're kind of give due credence to.

Josh Morse (HCA) My sense was, there wasn't actually sufficient evidence. I don't recall there being a question of equivalence.

Janna Friedly Yeah.

Josh Morse (HCA) Because that's much different. My recall was that there's actually not evidence.

Janna Friedly Yeah, and that's.

Josh Morse (HCA) But I could well be wrong, and if there's no.

Janna Friedly Well, that's what I was just sorry, Josh, I'm interrupting. That's what I was just looking at myself. There were 2 case series, I think, in the 2012 report for adrenal cancer and one noncomparative study of harms in 2023. And so there were no, there were no studies, no trials identified, that I'm saying, and that.

Jonathan G Sham What is? I'll go back to the evidence, for now.

Beth Shaw (CEbP) I can. Just yeah, there's no eligible comparative studies for adrenal.

Jonathan G Sham Oh.

Beth Shaw (CEbP) So this, there's really no comparative evidence for adrenal that met our criteria for this update.

Jonathan G Sham Maybe I missed.

Christoph Lee For billing tract, I think, Jonathan's right about biliary tract, though it does look like on, you know, looking at the evidence report for page 63, we said, but there's conditional recommendation, specific situations, even though it's based on low to moderate evidence quality I'm guessing that's for cholangiocarcinoma though.

Jonathan G Sham Maybe, perhaps I'm just misremembering. Beth, can you comment on the biliary tract? I'm going back to the evidence report and taking a look.

Beth Shaw (CEbP) Yeah, I'm just looking at the grade table, and I mean it does say that, you know it's equivalent to other options in many cases. We do kind of sit in the low to very low kind of certainty of evidence, so there's lots of uncertainty around that for a number of different reasons. But we've got some mixed results for survival, depending on what you're comparing it with. Similar progression-free survival, similar rates of intra-hepatic recurrence, and then, yeah, depending on, you know, the small hepatic cell carcinomas. But I think there's probably some equivalence, but lots of uncertainty around that generally, I would say.

Jonathan G Sham So, yeah, sorry I have a misspoke about adrenal. Possibly it's just biliary I was referring to. Again, we just, given that we can kind of run through these at the end of the last meeting I guess I just wanted to bring up the point of in the setting of, I guess a question of equivalency, and perhaps potentially lack of access to, perhaps, like hepatobiliary surgery in some parts of the State. I think we should at least consider broadening access to something that has the potential to be equivalent, given the available data.

Janna Friedly And with that I'm wondering if it, could we pull up?

Christoph Lee Cholangiocarcinoma is that can't be resected or?

Beth Shaw (CEbP) And that's really interesting, because we've got different types of hepatocellular carcinoma. So we, we've got statements on kind of a early stage, small liver cancer unresectable. So, you know, we've kind of split them out in different ways.

Christoph Lee And cholangio is specific to the biliary tracts.

Beth Shaw (CEbP) Okay.

Christoph Lee Rather than hepatocellular carcinoma, which is one of our.

Beth Shaw (CEbP) So, for the unresectable, intrahepatic cholangiocarcinoma is that what we're talking about here? Okay, so improved survival of data on progression-free survival, or other measures. So really improved survival based on one study, low certainty of evidence and that was for unresectable, intrahepatic cholangiocarcinoma.

Janna Friedly So do, do we want to, given that that discussion, should, should we take a another poll to see how people are? Our feeling about the biliary tract cancer, given that there, there is one, one study, one comparative study or intro

Josh Morse (HCA) You wanna do a vote a straw vote on biliary tract cancer?

Janna Friedly Yeah, let's revisit that. And then see, see if we need to, to revise that, this a decision before we take a final vote.

Josh Morse (HCA) Okay. So just a quick reminder here on voting, so full HTCC members are voting. Dr. Lo, you are not a voting member, so please don't vote on the strap holes or on the final review. Final votes here when we get there. So, I don't know, Val, do you wanna do this by voice vote, or do you have it or are you able to run a quick poll?

Val Hamann (HCA) Yeah, I can relaunch.

Josh Morse (HCA) This would be for biliary. Okay?

Val Hamann (HCA) Yep. Here that is.

Janna Friedly Okay. So it does, does look like some folks have changed our minds about coverage. So 80% cover with conditions. So, so with that, then, yeah.

Simon Lo Yeah. I'm just confused. Should I be voting for this one too?

Josh Morse (HCA) No, you should not be voting, Dr. Lo.

Simon Lo Okay. Got it.

Janna Friedly Did, did you vote for this one?

Simon Lo No, no, I was not sure I didn't. Yeah.

Janna Friedly Okay. Yup. Yup.

Josh Morse (HCA) Thank you. Dr. Lo.

Janna Friedly So, so given, that change, then Jonathan, maybe you can help us with, with language for cover, cover with conditions. Then, and I don't have the, I have just the summary of that, the one comparative study. So I don't have the specific criteria that they used in that study, or to be able to craft coverage with conditions.

Jonathan G Sham Which page is that on the evidence report?

Janna Friedly Well, what what I'm looking at is, is page 66, which is just the, just the table with the, the one comparative study. So we, I think we need to review.

Beth Shaw (CEbP) They describe it as being unresectable, intrahepatic cholangial carcinoma.

Jonathan G Sham Yeah, I mean, so, generally speaking, this is utilized in the setting of I get unresectable disease. Do you mind going to the pancreas just to see the verbiage that we use? I, I guess I'd like to make it mirror if you know as much as possible. Again, I think that.

Josh Morse (HCA) So I'm gonna copy this and move it to the bottom. Is, that that makes sense?

Janna Friedly Starting point.

Jonathan G Sham Sure, as a starting point. Yeah, I mean. So in again in cholangial carcinoma and the, there's not the same type of role of new adjuvant chemotherapy as there's an pancreas cancer. So I don't think we need the chemotherapy verbiage. I'm just looking at Beth's message here.

Janna Friedly Yeah. So it excluded metastatic.

Beth Shaw (CEbP) Yes, those are. That's the details from the trial. Well, the, the that we based that statement on.

Jonathan G Sham Yeah. Yeah. Yeah.

Janna Friedly So you, you could take out the and is either deemed, yeah, all of that. And non-metastatic disease.

Jonathan G Sham And I think it's pretty clear. There are some centers that utilize a size cut off similar to you know what we used to have in HCC. We took out, we took that out in HCC based on one of our the comments made at the last meeting. And so I guess I would favor also leaving out of size criteria for this one, and also lack of evidence and mentioning in the study.

Janna Friedly Yeah, I think given that there's, you know, just one study, it makes it difficult to come up with any criteria that are not included in that, that particular study is evidence-based. Any other comments or concerns about this language? Alright. Thank you for bringing that to our attention. And you know we can have more discussion as a committee about equivalents versus the evidence. But I think it, you know, in general, we are looking for evidence that that demonstrates effectiveness and if it's equivalent to an effective treatment, and in, in my mind that that does make it, yeah, effective in thinking about some of the equity issues, and access issues does become important if, if people are limited to access to the alternative treatment, if, if they are, if they are effective. But we that's a good discussion for, for the committee to have in general. But it sounds like, in this case there was, was evidence of effectiveness in any case, at least from one study.

Jonathan G Sham Thanks for taking another look at it. I appreciate it.

Janna Friedly Okay.

Josh Morse (HCA) Thank you.

Janna Friedly So, so let's now, any other before we take our final votes, then, now that we've updated our list? Okay, so let's, let's go ahead and do our final vote then, for the conditions that we deemed covered with conditions, with the language as written on this document.

Josh Morse (HCA) Yeah. And can we do a quick check in with Dr. Hearne? Chris, are you, can you hear me?

Chris Hearne I can hear you, yes.

Josh Morse (HCA) Okay, just wanna make sure that you are voting here on these final votes.

Chris Hearne I wasn't, I wasn't present at the original meeting, and I'm not sure that I understand it all well enough to give a reasonably informed vote.

Josh Morse (HCA) Okay.

Chris Hearne So I had thought to abstain.

Josh Morse (HCA) Thank you.

Janna Friedly And with that, Josh, we're still, we're still okay in terms of votes. Okay.

Josh Morse (HCA) We're okay. We have a quorum. We have excess of a quorum.

Janna Friedly Okay, okay, can, can we launch a poll? Yeah. Okay, great. And then we'll have a. So that's a hundred percent approval of the covered with conditions. And then we'll have a second vote for all of the tumors and the non-covered category.

Simon Lo So should I be voting this one.

Janna Friedly No, not both.

Simon Lo Okay.

Janna Friedly Okay, so 80% approval, so that passes as non-covered. Okay, great. Well, thank you for, for that good discussion and, and getting through those, I think next order of business, Josh is to review our previous business.

Josh Morse (HCA) The next order is to make sure you confirm guidelines.

Janna Friedly The coverage. Yes, yeah.

Josh Morse (HCA) Does your decision here align with professional society guidelines, and if not, if you could state your reason. For example, if you have the most current evidence available in this report, and similarly, a statement about the national coverage determination, and I do not think there is an NCD for SBRT from Medicare.

Janna Friedly Yeah, yeah. So there is no national coverage decision and in reviewing there are some guidelines that are specific for each different cancer type. And let me just pull up. Sorry, the, I had it up moment ago. And now, yeah, so, so there are several professional society guidelines, ASTRO and NCCN and a few others, including Nice, and in general for prostate, lung, pancreatic, and liver, there is coverage recommendations for, for conditions associated with, with those types. So they, I think our decisions are, can consistent with that. They, the in terms of the other, I guess. Sorry I'm scrolling through too many things. The other conditions, and there are some variable recommendations and limited, limited information available for, for the other, the other conditions there is one guideline that does suggest that for adrenal cancer it could be considered. But that was on that is only in 1 one guideline, the NCCN guideline. Otherwise for head and neck cancer and, and bone cancer there are only considered, insufficient for head and neck and bone for just for oligometasteses. So I think, in terms of our coverage decisions, for, are in line with the professional society guidelines to the extent that they are, cover the specifically conditions, but that they review the specific conditions that we reviewed, and then, in terms of the payer guidelines, there are again, no national coverage decisions. There are, we did review several payers and in general our recommendations are consistent with those as well United, Aetna and Cigna. None of those cover, for example, adrenal. And there isn't enough specificity in the categories that they, they cover to, to compare to some of the categories that we that we reviewed is non-uncovered. So I think the first my perspective, I think we are in line with the available guidelines and coverage decisions of other payers.

Simon Lo So how about Medicare and Medicaid?

Janna Friedly So, Medicare, there are no national coverage decisions. And Medicaid, Medicaid coverage is state is, you know, state coverage State by State coverage. So we don't review other States Medicaid coverage as part of this.

Simon Lo So this one doesn't affect Medicare, I don’t believe right, this this one?

Josh Morse (HCA) No, this decision does not affect Medicare. Great thanks, Dr. Friedly for the summary that's super thorough and helpful.

Janna Friedly Okay. Anything else, Josh, before we move on to?

Josh Morse (HCA) No, to conclude this, I'll just say this draft will be published for a 2 week comment period, as I stated at the beginning of the meeting. At that time, we'll be seeking, you know, any comments on the language itself, as far as intent goes, or any evidence that that was missed perhaps in the review process. So when the committee comes back, if there are questions about evidence that are brought up, those will be addressed as well as language, clarity, or intent issues, those are the 2 things that we'll be looking for when we consider those comments in the next hopefully in the next meeting. So I think we're, unless there's other questions about SBRT or the process at this point for SBRT, I think we're ready to move to the transcranial magnetic stimulation draft decision and a vote to make that final.

Janna Friedly Okay. And could we pull, pull that up, and just to to summarize, we had come up with a cover with conditions decision, and language. And in the public comments period there was a public comment that had asked us to review the number of sessions that we that we had allowed in our decision, which was up to 30, and they had the public comment had asked us to consider or suggested up to 36 sessions. We had had an initial discussion at the beginning of our last meeting, where we reviewed how we arrived at that 30 sessions, and that was in reviewing our discussion about this, that was based on our clinical experts information about what the maximum number would be appropriate, and the evidence that we reviewed. We had initially discussed at the last meeting that we felt that it was still appropriate for us to leave our decision as written with up to 30 up to 36 sessions, and that there was no evidence to increase to 36, and but we had not finalized that vote. We were going to do that at the end of the meeting. Are we able to pull that up just so that people can see it?

Josh Morse (HCA) Yep, pulling that up right now. Apologies for the delay here. So I this is the comment. Is that what you wanted to see or?

Janna Friedly Well, I was thinking that. Yes, that's helpful, that there so 34 to 36 sessions. And yeah, and so this is from Regence Blue Cross, suggesting that we that most of the protocols are up to 36 sessions. And, and then our language for the coverage decision. And we had up to 30 treatment sessions, and, and that was based on our clinical expert information that, that, that more than 30 some sessions was not, was not something that that was used and that 30 sessions was appropriate. Yeah, and there was no evidence, none of the, the protocols in the evidence that we reviewed were up to 36 sessions.

Simon Lo So I suppose I can sign up now right?

Janna Friedly Yes, thank you.

Josh Morse (HCA) Thank you so much, Dr. Lo. Appreciate your time.

Simon Lo Thank you.

Janna Friedly Any discussion from, from the group, or any questions or concerns?

Jonathan G Sham Just a general question. How often and kind of the public comments period do you see payers asking for broader coverage? Is that common?

Janna Friedly I don't know that I never seen that. I don't have an answer to that. I, it's it's a good question.

Josh Morse (HCA) And this comment is from one of our contractors, who, they are thinking ahead about implementation.

Jonathan G Sham Yeah, I, yeah.

Josh Morse (HCA)	Typically, when they're commenting they're thinking, I think, about what are they, what are their current policies? What impacts? What have they experienced?
Christoph Lee	Yeah, it is interesting. Looking back at the evidence report from that session, most payers do up to 36.
Janna Friedly	And if I recall that's sorry, let me, let me pull up that transcript again, since we had had a discussion about this specifically.
Clint Daniels	This is Clint. I thought the expert had said that the longer treatment plans were based on basically outdated technology that hasn't kept up with the current standards. So I thought she said it was a lot fewer visits now was more standard.
Janna Friedly	Hmm! Yeah. So the, the discussion from the transcript, there are applications with a devices that we currently use in practice that allow us to treat patients much more quickly and as few as 5 to 10 sessions. So that 30 is on some of the older devices that were studied in the initial FDA labeling. And so, even up to 30, I think from their perspective, was, was beyond what you would actually need. Okay. Should we at this point go ahead and take a vote on this and see where we're at? Unless there's any other discussion about this?
Josh Morse (HCA)	So is this a final vote, Janna?
Janna Friedly	This is a final vote. Yes.
Josh Morse (HCA)	Okay, thank you.
Janna Friedly	Okay, so 100% final vote for this wording.
Josh Morse (HCA)	Okay, so the TMS decision is approved as final.
Janna Friedly	Yes.
Josh Morse (HCA)	I believe that concludes our business for today.
Janna Friedly	Great. Well, thank you, everybody for taking the time today to for this extra, extra meeting. I appreciate it. And, Josh, when is our next meeting? Do we have that?
Josh Morse (HCA)	July 21 is, our team will correct me if I'm wrong. Friday 21st it's the hyaluronic acid, platelet-rich plasma topic, which is it's a dense one. I think it's a little more straightforward than the SBRT with all of the conditions, this is really focused on one condition which is osteoarthritis of the knee. There's quite a bit of information to go through with some, which treatment compared to various comparators and then compared to each other. So it's gonna take some time and some logical thinking to wait through it. But it's the report is very nearly out there, if you're interested in some summer reading between now and then. Got a month, so.
Janna Friedly	Okay, great. Well, thank you everybody. Enjoy this nice rest of the nice summer day.
Josh Morse (HCA)	Thank you very much. Really appreciate your time today.
Janna Friedly	Thank you. Bye. Bye.
Clint Daniels	Bye!
Tony Yen	Thank you, Janna and Josh.
Janna Friedly	Okay, buh-bye.