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Health Technology Clinical Committee Public Meeting
July 11, 2014

REC: The broadcast is now starting. All attendees are in listen-only mode.

Craig Blackmore: Test, test, test. This is Blackmore testing the microphone. Can you hear me?

Christine Masters: Dr. Blackmore, this is Christine Masters in Olympia, can you hear me?

Craig Blackmore: I can hear you, Christine, can you hear me?

Christine Masters: You sound great, and Josh is here.

Josh Morse: Craig, are you registered on the Webinar?

Christine Masters: You are not showing up on our list.

Craig Blackmore: Well, I just signed on.

Josh Morse: No, you are showing now, sorry.

Christine Masters: Thank you, Rhonda, for remembering, and good morning to everyone else who has joined us today. The Webinar will start in a moment.

Good morning, and welcome to the Health Technology Assessment Committee public meeting and Dr. Blackmore would you like to begin?

Craig Blackmore: This is Dr. Blackmore, can you hear me?

Christine Masters: Yes, I can.

Craig Blackmore: Alright, I am going to check and see if we have a quorum, and then if so, we will call the meeting to order. It looks like from the Webinar, as best I can tell, we have Marie-Annette Brown, Michelle Simon, Richard Phillips, and myself. Are there any other committee members online yet who I have not identified?

Joann Elmore: Hi, Craig. This is Joann Elmore. I am not on the web, but I am on the phone.

Craig Blackmore: But, you are on the phone. Okay, very good. Okay, very good. Are there any other committee members there?

Rhonda Stone: We see Richard Phillips, is a member of your committee? Yes, he is.

Christine Masters: Yes, he is.

Rhonda Stone: Okay, and we are having a little difficulty with his audio at this time. So, we will see if we can work that out.

Craig Blackmore: Okay, and then let's give another minute and see if we cannot get a couple more members of the committee online, or at least on the phone. Either way is fine.

Rhonda Stone: Dr. Phillips, can you hear us now?

Josh Morse: It looks like Richard is trying to sign back on.

Craig Blackmore: Okay. We still need at least one if not a couple more committee members here to have a quorum, and we have heard from others that we think they are going to be on, right?

Josh Morse: Yeah.

Craig Blackmore: Okay. So, we will just give a couple of minutes.

Rhonda Stone: Dr. Simon, can you hear me now?

Michelle Simon: Yes, I can hear you.

Rhonda Stone: Okay, we have unmuted you briefly. When we unmute everyone at once, we get terrible feedback. So, we are trying to be selective. Since we know you are connected now, I am going to check some of the other members.

Christine Masters: And then the other thing that we need everyone to do, if we unmute you, we need to make sure that you are not using your speakerphone. Please use your handsets. That will improve the audio quality.

Joann Elmore: I will just keep it on mute the whole time that I am on a speakerphone. I am not a hand phone. This is Joann Elmore. I will just keep it on mute.

Josh Morse: Okay, Joann. Thanks. You are not actually... we are not hearing any feedback from your phone, I do not think.

Joann Elmore: Right, yeah.

Rhonda Stone: Dr. Brown, can you hear us?

Marie Brown: Yes, I can.

Rhonda Stone: Okay, perfect. Dr. Phillips, any luck yet with your head (inaudible)?

Richard Phillips: I just got it going. I do not know what was going on there.

Christine Masters: Woo hoo.

Richard Phillips: I rebooted and it seemed to work.

Craig Blackmore: We can hear you fine.

Christine Masters: Thank you.

Craig Blackmore: Well, sometimes it takes a while to figure these things out. So, we will give people a minute or two to get online.

Josh Morse: I believe at the moment we have five committee members signed on.

Craig Blackmore: Yes.

Josh Morse: And we can do a voice (inaudible) here in a moment. If anybody is not visible online, let's do a roll call.

Joann Elmore: And again to verify, you do not need me online, do you, Craig? I mean, I have got all the materials here.

Craig Blackmore: No, no. I just... I need you present on the phone. That is great.

Joann Elmore: Okay, thanks.

Josh Morse: Do you have your email open, Christine?

Christine Masters: I do not.

Rhonda Stone: Here, we are getting more people.

Josh Morse: Are we? There we go. Dr. Standaert's on the line now.

Craig Blackmore: Dr. Standaert, can you hear us?

Chris Standaert: I can, yeah.

Craig Blackmore: Very good, and we just picked up Michael Souter. Dr. Souter, can you hear us?

Christine Masters: He is not on.

Craig Blackmore: He is on my list.

Christine Masters: He is on the list but he has not dialed in. We do not have audio connection with him yet.

Carson Odegard: This is Carson Odegard.

Craig Blackmore: Carson, that you?

Carson Odegard: Yep.

Craig Blackmore: Alright.

Carson Odegard: Can you hear me?

Craig Blackmore: We can.

Carson Odegard: Good, yeah.

Craig Blackmore: Okay. Let's... let's... I think we have a quorum, but let's do a roll call just to confirm and to see who is present and get an understanding of this, if they are using the phone or internet.

Rhonda Stone: Before we start with roll call, we are going to do a quick unmute of all of the committee members. We will let you know when that is finished. There we go. Just a quick reminder to everyone that you are unmuted. We will pick up all of your background noise.

Josh Morse: And the meeting is being recorded, for those of you on the phone today. So, it appears that everybody on the committee is unmuted who is visible online, and Dr. Elmore, I believe you are on the phone and you are not visible on our checklist. So, let's go through and do a verbal check in. I will just call names, and if you can verbally respond, we'll figure out if you have, if we have a good audio connection and we will just know that you are here. So, Dr. Blackmore?

Craig Blackmore: Yes, I am here.

Josh Morse: Dr. Brown?

Marie Brown: Yes, I am here.

Josh Morse: Dr. Elmore?

Joann Elmore: Here.

Josh Morse: Okay, Dr. McCulloch? I don't believe David is here today. Dr. Odegard?

Carson Odegard: Yes, I am here.

- Josh Morse: Thank you. Dr. Phillips? Dr. Phillips?
- Richard Phillips: I'm here.
- Josh Morse: Dr. Schwartz? Dr. Simon?
- Michelle Simon: Present.
- Josh Morse: Dr. Souter? Okay, we see Dr. Souter, but we are not... we do not have an audio connection, it sounds like, right now with Dr. Souter, but he is present online, and we will go, Dr. Standaert?
- Chris Standaert: Yep.
- Josh Morse: Dr. Walsh.
- Christine Masters: He cannot be contacted until (inaudible).
- Josh Morse: Okay.
- Craig Blackmore: Okay, well we have a quorum. That has got...
- Josh Morse: We've got a quorum.
- Craig Blackmore: ...eight, eight members, including Dr. Souter. It is even seven without, so that would be a quorum. So, I am going to call the meeting to order, and we will continue to work on the audio connection with Dr. Souter. So, this is an open public meeting.
- Welcome to the Health Technology Clinical Committee meeting. We will be conducting it over the phone, obviously. We have a relatively short agenda this morning. This is really a meeting to focus on what we addressed at the previous meeting, that would be the meeting where we made a decision about the proton beam therapy, sorry. So, the two... well, going through the agenda, the first thing on the agenda is program updates, and I am not sure we have any updates we need to go through. Josh, is there anything we need to report?
- Josh Morse: The only update is the next public... the next review meeting, action meeting, is now scheduled for November. We do have the September meeting on the calendar for the committee retreat, and those are the only updates right now. Thank you.
- Craig Blackmore: Alright, very good. We will move on. The first item, then under the Health Technology Assessment previous meeting business is approval or discussion of the meeting minutes of our May 16 meeting. So, the draft meeting minutes have been distributed to the committee members and made available to the public and so I will call that to the attention of the committee members and ask for any comments on the draft minutes or a motion to approve the minutes and

just sort of procedurally, since we are on the phone, you are going to have to identify yourselves, as you address the group. So, discussion and/or motion to approve the meeting minutes from May 16, 2014.

Richard Phillips: Alright, this is Richard Phillips. The minutes that went out were labeled May 2nd, not May 16th, but anyway, I read them and I approve them. I would make a motion that we accept them.

Craig Blackmore: Alright, thank you. Is there a second.

Carson Odegard: Carson Odegard, second.

Craig Blackmore: Very good and I will now ask for a vote to approve the minutes and again, I think because of our format here, we probably want to do that by roll call. So, Josh or Christine.

Josh Morse: I will get a roll call.

Craig Blackmore: Can I get you to do a roll call please?

Josh Morse: Yes. So, Dr. Blackmore?

Craig Blackmore: Approve.

Josh Morse: Dr. Brown?

Marie Brown: Approve.

Josh Morse: Dr. Elmore?

Joann Elmore: Approve.

Josh Morse: Dr. Odegard?

Carson Odegard: Approve.

Josh Morse: Dr. Phillips?

Richard Phillips: Approve.

Josh Morse: Dr. Schwartz? I don't believe he is here. Dr. Simon?

Michelle Simon: Approve.

Josh Morse: Dr. Souter? We still haven't sorted out the audio with Mike.

Rhonda Stone: He can send an approval through the (inaudible) that you've done.

- Josh Morse: Okay. He approves in writing. Dr. Standaert?
- Chris Standaert: Approve.
- Josh Morse: Dr. Walsh?
- Kevin Walsh: Approve.
- Josh Morse: Thank you, that is all approved.
- Craig Blackmore: Alright, very good. So, the next item for business is the draft findings and decision document on proton beam therapy and again, this has been distributed to the committee members and made available to the public on the website. I will now solicit discussion on this document and I will also start the discussion because I do believe we need to correct this a little bit.
- In looking at the transcript from the previous meeting, as well as sort of my memory of that meeting, I will call your attention to, under limitations of coverage where it says central nervous system and there's a parenthesis and some text, it says e.g. brain, spine, paraspinal, and that has been edited. My memory and my interpretation of the transcript is that we, as a committee, meant for that to simply say central nervous system tumors without the parenthetical expression. In our wordsmithing, we honed that down to central nervous system tumors without other qualifiers. So, I would suggest as an edit to this document that it be what I just stated that that line reads, central nervous system tumors and, without any further specification. Thoughts on that or any aspect of this draft document from the committee members?
- Marie Brown: I have a question, this is Dr. Brown, about the point. We have it in our rules that involvement in clinical trials is... is covered and we do not need to restate that. Is registry included in that, as well?
- Craig Blackmore: So, I think that you are... you are asking... that is a question not for the committee as much as for the... the agency directors and staff as to their ability to fund patients in research trials outside of our recommendations. Is that a fair statement?
- Marie Brown: Yes, just for the record, what our policy is.
- Craig Blackmore: Okay. I do not know if we have, I don't know if we have personnel on the phone to answer that at this time.
- Josh Morse: So, this is Josh Morse. The agencies, the Health Technology Assessment law provides that the agencies can provide access for a patient or a covered member through a clinical trial for services that are not covered by the HTCC. What that... that does not limit them to trials, you know, type whether it is a registry or otherwise. So, it would be the agency's decision, basically, if they chose to cover, you know, participation in a registry trial, but it is not, I will leave

it at that. We do have, I believe, Dr. Lessler may be available on the line. I am not sure if we have an audio connection, but...

Craig Blackmore: Well, does that... does that answer your question?

Marie Brown: Yes.

Craig Blackmore: Dr. Brown? Okay. Any other comments or questions on the... on the document? If there is no... if there is no further comments or questions, I would accept a motion to approve or...

Josh Morse: Craig?

Craig Blackmore: Yeah.

Josh Morse: Craig, I have a... this is Josh. I have a question. So, the document, the draft version I am looking at then... the edit that I would make based on this would be the third bullet under covered benefit with conditions would read central nervous system tumors, is that correct?

Craig Blackmore: Could... could you repeat that Josh? I had some feedback.

Josh Morse: Central nervous tumors would be the third bullet.

Craig Blackmore: Yes.

Josh Morse: Okay. Then, I... I... under pediatric, we currently have the term pediatric cancers, should cancers be tumors?

Craig Blackmore: Well, you know, I... I think in looking at this document, pediatric cancers would mean cancers in any part of the body in children, and then central nervous systems tumors would imply that if you did not meet the category of pediatric cancers but you were a tumor of any age group in the central nervous system, that you would... that it would... the coverage would apply.

Josh Morse: Got you. Thank you.

Craig Blackmore: So, these are... these are... these are... bullets points are 'or' not 'and.' You do not have to be an ocular cancer and a pediatric cancer. You could be an... or. So, if you did not qualify under pediatric cancer, you could qualify under central nervous system cancer or one of the other categories.

Josh Morse: Okay, thanks, Craig.

Christine Masters: We also had a comment from Dr. Schwartz. He has some contributions about the tumor versus (inaudible). He says, yes, yes, yes, the tumor versus cancer question.

Craig Blackmore: So, he...

Josh Morse: Can you type in your comfort with the exception Dr. Blackmore gave, Seth?

Craig Blackmore: So, are you guys receiving input from him?

Josh Morse: Yeah, Dr. Schwartz is typing in. Apparently, he...

Craig Blackmore: Okay.

Josh Morse: ...we are unable to main... he is able to hear us, but we cannot hear him.

Craig Blackmore: Okay.

Josh Morse: So, he has written back, here is his comment. In some of the text it says CNS tumors and in some it says CNS cancer. It should be tumor.

Craig Blackmore: Okay.

Josh Morse: And to... this... the line that we have changed that line to... the wording is now central nervous system tumors without the information in the parentheses.

Craig Blackmore: So, that would seem to meet his concern.

Josh Morse: I believe so.

Craig Blackmore: Or maybe, that is... he could type in to let us know if we thin..., if he thinks we have addressed that.

Carson Odegard: Craig?

Craig Blackmore: Yeah.

Carson Odegard: Carson Odegard.

Craig Blackmore: Yep.

Carson Odegard: Seth cannot... if his audio is... is off, or, or it is listen only, he may want to type in the... the other access code and then you can type 20 and it will come up. So, there are two access codes.

Craig Blackmore: Okay. Hopefully, he can hear that.

Carson Odegard: And, so the other access code would be the 136 code and then type in 20#.

Craig Blackmore: Okay. So, I think we have addressed his concern and again, I... I reviewed the transcript, and that is what we indicated in... in the meeting. So, we are not changing anything. We are just clarifying what our decision was at that time.

Are there other concerns or comments about the documents right now? Josh, please let me know if you get any further feedback from Dr. Schwartz.

Josh Morse: Yep, we are watching for Dr. Schwartz and Dr. Souter is also having similar audio issues, but we are waiting to see if he is now available.

Michael Souter: I'm just trying to talk now, can you hear me?

Craig Blackmore: There he is.

Josh Morse: There he is. We can hear you now.

Michael Souter: Okay, good, thanks.

Craig Blackmore: The wonders of modern technology.

Josh Morse: Yes, complicated technology. It looks like we may have Seth here in a moment.

Christine Masters: If his phone is green, he will have access, but right now it is gray so he does not have access.

Josh Morse: So, Seth writes back, yes it does, but it... okay. We just need to be clear that it says tumors, but to clarify for the circle, it will say central nervous system tumors. For the first two bullets it will read ocular cancers and the second bullet will read pediatric cancers. That is, if you are able to see the screen or the version that was emailed to the committee, the one change that we are making would be to the third bullet to read central nervous system tumors.

Craig Blackmore: Okay, and then it, if I'm understanding this correctly from this document, we had originally had ocular tumors and there was an edit made to that, is that correct, Josh?

Josh Morse: Correct.

Craig Blackmore: On the first bullet point.

Josh Morse: Well, the, the document, let me verify that. Craig, the document has published in the draft, and it said ocular cancers.

Craig Blackmore: Okay. There is a... on the second page under HTCC coverage vote and formal action, the word tumor has been edited out and replaced with the word cancer. I am not sure at what point that edit occurred.

Josh Morse: Yeah, this... so the... the document as the committee left it actually I am holding. So, the way it was typed up by Margaret on May 16th, HTCC coverage wording that was on the screen for you read ocular pediatric CNS. So, the term tumor or cancer was not present in the... in the actual document, as it was typed up. In the original typing up of the minutes, the word tumor was put into the

documentation of what was done in the meeting and then when the draft language was typed for use in implementation, the word cancer was used instead...

Craig Blackmore: Okay.

Josh Morse: ...of tumors, but that is why you see different, differences there.

Craig Blackmore: Okay. So, so... we can leave it as central nervous system tumors, pediatric cancers, and then I would like Dr. Schwartz to weigh in on the first bullet point if cancers is appropriate or if tumors would be more appropriate in that line. Seth, can you either talk to us or email, type in.

Josh Morse: Seth has indicated in his typed feedback, I think cancers is okay for the ocular.

Craig Blackmore: Okay. Then we will go with what is on the first page of the document. Under HTCC reimbursement determination. The only line that will be different is the third bullet point, which will now read central nervous system tumors. Any further discussion on this?

Marie Brown: This is Marie-Annette Brown. The email from Michael Stevidge suggested a more specific clarification, one that says, this in my judgment should be clarified and limited to primary, meaning nonmetastatic, situations, non lymphedematous CNS malignant tumors or if metastatic conventional external beam radiation and/or stereotactics, tactics, radiosurgery have failed in the absence of other progressive systemic metastasis.

Craig Blackmore: Any other committee members have thoughts on that?

Marie Brown: The question is, is that something we want to consider or not?

Craig Blackmore: Well, my... my memory and... and... and after reviewing the transcript of the last meeting, my belief is that at the time, we wished not to limit... to not be that specific in terms of primary versus metastatic central nervous system cancers, but I would solicit input from other committee members about their understanding.

Michael Souter: I... I concur. I do not think that we have made that limitation. I mean, a lot of consideration of use of this is because of the site and the additional side effects of focused therapy elsewhere. I know that the medical directors have some considerations, some concerns about metastatic tumors, but I do not think we actually were that specific in addressing it.

Craig Blackmore: Yeah. Any other thoughts.

Chris Standaert: This is Chris... this is Chris Standaert. I would agree with what Dr. Souter said. I think we did not make a distinction and I think... I could see the clinical circumstance where even in a metastatic case you still may want to treat a focal

- CNS tumor with this method. I do not think we had the data, frankly, to make a distinction along those lines, either.
- Kevin Walsh: I... I... this is Kevin Walsh. I agree. I think the... I think the pertinent point is, we did not have... there was not evidence to distinguish. So, it would be, I think it is going to be out of bounds for us to go back now and consider caveat that were not presented to us.
- Craig Blackmore: Okay, any other concerns? Okay. Well, I would... I would solicit a motion to approve this.
- Christine Masters: Dr. Schwartz, I just wanted to let you know that you have been unmuted and you can speak now.
- Craig Blackmore: Okay, well I... I would... I would solicit a motion to approve the amended documents or further discussion.
- Chris Standaert: Motion to approve.
- Michael Souter: Second.
- Craig Blackmore: So, who was the first voice?
- Chris Standaert: Dr.... Dr. Standaert.
- Craig Blackmore: Okay, and then that was Dr. Souter, I believe who seconded?
- Michael Souter: Yes. Right.
- Craig Blackmore: Okay. Let's have a vote and again, I believe we should go by roll call.
- Josh Morse: Okay. This is the vote to approve the final findings and decisions for proton beam therapy. Dr. Blackmore?
- Craig Blackmore: It is for the amended... amended, edited version that we have discussed, and I vote to approve.
- Josh Morse: Thank you. Dr. Brown?
- Marie Brown: I approve.
- Josh Morse: Dr. Elmore?
- Joann Elmore: I approve.
- Josh Morse: Dr. Odegard.
- Carson Odegard: I approve.

Josh Morse: Dr. Phillips?

Richard Phillips: I approve.

Josh Morse: Dr. Schwartz? You can send in... I am sorry, Seth. We still do not have audio with you. He approves, okay. Dr. Simon.

Michelle Simon: I approve.

Josh Morse: Dr. Souter.

Michael Souter: I approve.

Josh Morse: Dr. Standaert?

Chris Standaert: I approve.

Josh Morse: Dr. Walsh.

Kevin Walsh: I approve.

Josh Morse: Okay, that is everybody approving. Thank you.

Craig Blackmore: Alright, thank you, and I believe that was our last item of business. Josh, is there anything we have left out?

Josh Morse: No, Craig. I think we are good. I thank you very much for your attendance this morning and for bearing with us with our... our new technology here.

Craig Blackmore: Alright. We are adjourned. Thank you all.