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Health Technology Clinical Committee Public Meeting

July 14, 2017

Chris Standaert: Well, I don't know how many of you were in the webinar thing, but we've updated them now with our agenda. The purpose of the call is to [inaudible] previous meeting business is what we do. So, we talk about our [inaudible] and go through those. And then we discuss our decisions from the last meeting in May. So, if we have a quorum, we can go ahead. So, the first order of business is the minutes, which were available on the website. You can pull them up. I [inaudible].

[Technical difficulties]

Josh Morse: So, the minutes were sent out, and they are available on the website, as well.

Chris Standaert: I read through the minutes. If people have a minute to think about them or find them online or whatever they were doing to look at them, make sure no typos or errors. [inaudible]. Anybody have any questions or comments on the minutes? Corrections? I don't know. Are people [inaudible] approve them would be appreciated.

Laurie Mischley: This is Laurie. I move to approve.

Male: [inaudible] I second.

Chris Standaert: OK. All in favor, say aye.

Group: Aye.

Josh Morse: We need to get a voice count. So, I'll go through.

Chris Standaert: We need a roll call.

Josh Morse: Yes. So, OK. For minutes for approval, I will say your name. If you approve, just please say yes or aye. Dr. Brown? Dr. Elmore?

Joann Elmore: Yes.

Josh Morse: Dr. Hearne?

Chris Hearne: Yes.

Josh Morse: Mischley?

Female: Yes.

Josh Morse: Odegard?

Carson Odegard: Yes.

Josh Morse: Schwartz?

Male: Yes.

Josh Morse: Standaert?

Chris Standaert: Yes.

Josh Morse: Walsh?

Kevin Walsh: Yes.

Josh Morse: Rege?

Sheila Rege: Yes.

Josh Morse: Yen?

Tony Yen: Yes.

Josh Morse: Bramhall?

John Bramhall: Yes.

Josh Morse: OK. That's ten yeses. Thank you.

- Chris Standaert: Next, we move onto our decision. The first one is [inaudible] on selected treatments for varicose veins, and we received two comments on those. Can you pull up the comments? The first one is from Dr. Brian Ferris, Lake Washington Vascular Surgeons. He had a question on our language regarding the 3 mm and the truncal saphenous veins. He also asked that we include a specific product, as indicated treatment for truncal reflux. Josh, you were going to talk to him about clarification about what he was stating in that first part?
- Josh Morse: Yes. We connected, but I did not get... we did not connect over this issue. So, I don't have an update for you from what he was thinking about this.
- Chris Standaert: We debated the truncal saphenous question when we were talking about this, but I think [inaudible] our language got convoluted a bit, as we were trying to do that. I wasn't sure from this gentleman's comment whether he was needing for us to be more inclusive or more restrictive in our language. I couldn't quite tell. That's why I was hoping you could clarify. How do other people take this comment?
- Tony Yen: It seems like he wants to include his particular product. I think that's kind of the intent of this statement.
- Chris Standaert: [inaudible] There are two it looks like. There is the one about the vascular thing, and that is the [inaudible] particular product.
- Tony Yen: Yeah. I apologize. The part that I was really interpreting was really the last... the second part, which is [inaudible] product. It seems like Brian wants to include that part.
- Gregory Brown: [inaudible]
- Chris Standaert: Yeah. I don't recall any specific language of that particular product coming up on our discussion. I would have a big problem saying we should include language regarding specific names or branded device without, you know, specific study language or other things on that in our view that I don't recall seeing.
- Seth Schwartz: I think [inaudible]. It's one of two scenarios. It's either something we already talked about and it was just a name

- brand which says we shouldn't be more specific or something we had talked about in which case we would include it. So, I don't see anywhere [inaudible] include it.
- Chris Standaert: You don't see any way that we would want to? Is that what you said?
- Seth Schwartz: Either it's just a brand name or something that we've already covered [inaudible]. Or [inaudible] data on, which we can't include. So, either way, I, uh, I don't think it should be included.
- Chris Standaert: I would agree with you. I thought [crosstalk]. Huh? Sorry.
- Laurie Mischley: This is Laurie. I just agree.
- Chris Standaert: The first part, how do people interpret that?
- Gregory Brown: I can't interpret it either way.
- Male: I'm not a committee member, but I'm [inaudible] able to make just a comment?
- Chris Standaert: Can you identify yourself?
- Male: Sure. I'm [inaudible]. I'm a medical science liaison for [inaudible], and what I [crosstalk].
- Chris Standaert: So, what is, what [inaudible]?
- Male: [crosstalk]
- Chris Standaert: And you manufacture what exactly that's relating to our discussion?
- Male: [inaudible]
- Chris Standaert: Oh, you manufacture that product. OK. So, your comment pertaining to?
- Male: I just wanted to make a point of clarification about kind of the [inaudible], which is a comment. So, uh, one of the things [inaudible] was, you know, [inaudible] clarity on why [inaudible]. When I read this, I think it was because when you looked at the original Health Technology Assessment for the [inaudible] you know, pointed out has one of the

[inaudible]. Within that umbrella, it breaks it down into liquid [inaudible] sclerotherapy and within sclerotherapy, there is [inaudible] which is [inaudible], but [inaudible] for truncal vein, thermal [inaudible], which is [inaudible] frequency laser ablation, therapy also is a product approved with [inaudible], and I actually [inaudible]. I attended the original meeting, and afterwards I [inaudible] original language of the coverage determination that you guys were including truncal veins initially, but then as the conversation kind of evolved and focused on ensuring you're [inaudible], you were trying to clarify specifically tributary varicose veins and anything that was greater than or equal to 3 mm, but then you guys [inaudible] kind of how the conversation was going, you omitted the truncal vein here, which is definitely the main indication of varicose veins. So, I think that's kind of where Dr. Ferris was coming from.

Chris Standaert: OK. Thank you.

Male: Chris?

Chris Standaert: Yes.

Male: [crosstalk] in the evidence report. It was specifically addressed through initial comments in the draft earlier, and the vendor [inaudible] studies previously, and it is... I may have mentioned it that the evidence report.

Chris Standaert: OK.

Joann Elmore: This is Joann. Whoever is typing this, [inaudible] and then a [inaudible] for the group, is this [inaudible] indications [inaudible] delete the word tributary and just have the indication varicose veins greater than 3 mm and the other two [inaudible]?

Chris Standaert: That's what I don't know.

Male: [inaudible]

Chris Standaert: So, if we're going to have, I'm sorry. So, we, excuse me, sir. We need to discuss this as a committee. I mean, we need to...

Male: Sure.

- Chris Standaert: [crosstalk] This is our discussion if you don't mind.
- Male: Sure. Absolutely.
- Chris Standaert: So, committee people.
- Gregory Brown: Dr. Ferris' language is not specific enough for me to interpret what he's suggesting.
- Chris Standaert: That's my [inaudible] with it, as well, yeah.
- Gregory Brown: So, I think Joann's observation is logical, but it doesn't seem [inaudible] into the language.
- Sheila Rege: This is Sheila, and I kind of worry about including one specific manufactured product. What if there is another manufacturer that comes out with a similar product.
- Chris Standaert: Yeah.
- Joann Elmore: This is Joann, and I agree with you on that, and we would have had to have viewed specific evidence on this specific product. My comment was just about the truncal question, and I had sent an email to Josh asking him if there's a way that he can have easy access to primary articles, because last night I wanted to pull up the articles to see, you know, what was their eligibility and inclusion criteria. I wanted to be up to date, and that was potentially [inaudible] question about whether [inaudible] indications need to be slightly [inaudible] by it. So, [inaudible].
- Seth Schwartz: This is Seth again. I guess I'm a little [inaudible]. So, I heard that we did review evidence on this product, but I guess my question is, is this product not already covered under what we already approved, or is this something different that we've not included in our coverage decision?
- Josh Morse: This is Josh and the answer is this product would be covered under your current conditions, because it is a treatment in the realm of sclerotherapy. This is a specific [inaudible] product for that, under that category.
- Seth Schwartz: OK. So, that meaning it's already approved. We just didn't call it out by name?
- Josh Morse: That is my interpretation, yes.

Chris Standaert: And I [crosstalk] Sheila said and what you're saying, that we don't approve a specific brand of product unless that is the full focus of the review, because of the class or content or treatment. Like, we didn't approve Botox. We approved onabotulinumtoxinA on the assumption that, like Sheila said, and like [inaudible] saying that there are other variants of the same thing that may develop or may become available, and we're not intending to restrict it to a single device that is [inaudible].

Seth Schwartz: So, I think that part's not hard. I think it's easy for us to say that we don't... call attention to a specific product. It's already covered under the determination. I think the bigger question is the question of whether or not tributary veins [inaudible]. I think that's something that I cannot recall exactly, but we need to know, what exact evidence that we looked at. Did they stratify tributary and that's what we're talking about. That's what the determination is about. Or did they not, and then we sort of accidentally did that, and that's what, I guess we need to do, because if that, if that's the question, like Joann suggested, then we could get rid of the term tributary, but we don't want to do that if it's not appropriate based on the [inaudible] that we received. So, that's what I'm not sure about.

Chris Standaert: Right. I think the issue we're in, in part, was the saphenous vein is greater than 3 mm to begin with. I remember that part of our conversation, and so that number didn't work very well with that vein.

Sheila Rege: I recall our expert having an opinion, and I can't remember exactly what, on the tributary issue.

Chris Standaert: I recall that, too.

Joann Elmore: I'm going to suggest to Josh, this is Joann, that perhaps in the future, we have the clinical experts join for these brief 30 minute calls. So, looking at the [inaudible] recommendations, they did not specify tributary under indications. They just said varicose veins [inaudible], and looking at the [inaudible] the other [inaudible] were listed as just varicose veins [inaudible]. So, I also wonder about the tributary.

Chris Standaert: Hmm. Probably those two [inaudible] take out that word.

- Josh Morse: Take out the word tributary.
- Chris Standaert: Yeah, probably make a change to take out that word.
- Kevin Walsh: Chris, is that how you read this letter, that he is suggesting that we remove the word tributary?
- Chris Standaert: I'm not sure how to read the letter. I find the letter confusing, and when I... Josh and I talked about it, and I was hoping to get clarification for [inaudible], because I find it confusing. I don't know what he is suggesting there. I'm not [inaudible] saphenous veins, as it pertains to thermal ablation, and I don't know if that means we should be restricting thermal ablation to truncal saphenous vein in his opinion, or whether we should be expanding our language to include truncal vein. That's what I'm a bit confused about. We have all of our technologies, all of them [inaudible] without sort of one versus the other for a different indication, and I think we were trying to be...
- Male: I guess I feel like [inaudible] to either be on the call or to have clarified his request in more detail, and without that, we can't, I don't feel I can act on this letter, because otherwise, I feel like I'm interpreting what he's saying as opposed to responding to what he said, and I don't want to do that.
- Chris Standaert: No. I agree. I agree. I don't want to try to, I'm not... you know, I'm not quite sure what he's suggesting.
- Male: Well, we don't want to approve the product itself by now. I recommend we disregard the first half of this letter, as well, because it's not [inaudible] for us to understand his intent.
- Chris Standaert: What do other people think? Do they think we should be concerned in changing our language? I have trouble doing that [inaudible] letter. I agree with Kevin. I don't quite understand the [inaudible] of it.
- Sheila Rege: I would be in favor, this is Sheila. I would be in favor of keeping it as is, because we are confused, and I recall something with the expert and how we [inaudible] it.

- Chris Standaert: Yeah. The language was deliberate when we made it, and we were trying not to get ourselves caught in a situation that was more [inaudible].
- Laurie Mischley: This is Laurie. If I recall what the expert said, it was just that because the trouble happens with a larger vein, it was already covered. So, we were fine. I mean, that... that was how I think we got there. We weren't excluding that.
- Chris Standaert: So, would our language exclude a truncal saphenous varicosity? That's what [inaudible] or is that part of the question?
- Josh Morse: I hate to ask the question, Chris. This is Josh. As I read this and listen to the conversation, I think that [inaudible] indications include the truncal saphenous and if they do not, then your intent is to allow treatment for that, do you need to modify the language? Could you add the bullet above the tributary varicose vein bullet with treatment of saphenous, truncal saphenous vein or tributary veins with the [inaudible] that follow?
- Chris Standaert: I think what we did is [inaudible] but with the treatments for varicose veins, meaning that you can treat varicose veins but that if you treat a tributary, it has to be greater than 3 mm. So, I don't know if our [inaudible] varicosities are covered, and then we clarify if on a tributary it had to be beyond a certain diameter, but I don't know that our intent was to exclude truncal varicosities. I don't know, does this language read as though we included that the way we worded it?
- Joann Elmore: This is Joann. That's why I wondered about deleting the word tributary.
- Chris Standaert: No. Well, but we put tributary varicosities, because the 3 mm refers to the tributary varicosity, right? So, [inaudible] varicosities greater than 3 mm means every [inaudible] vein, right? That's why we, that's why we, we clarified that for tributary varicosities, and I think we were thinking that by saying we can treat varicose veins, we were including the ability to treat a truncal varicosities, which all, by definition, are greater than 3 mm, because the vein itself is. So, do we need the line saying truncal varicosities under our indication in addition to tributary varicosities greater than 3 mm? We didn't want to include all varicosities greater

than 3 mm, because that means you could treat every saphenous vein essentially. Do we need another line that says truncal varicosities in our indications, or is that included in our first statement that varicose veins are covered?

Joann Elmore: The way it is written, no. Right now, the indication is it has to be a tributary vein, but it's [inaudible]. The current indication is that it has to be a tributary, as it is written with two additional 'and' requirements. A-N-D-. If we word it as a varicose vein greater than or equal to 3 mm, that's covered, you know, all of them.

Chris Standaert: Yeah, but we chose not to do that deliberately, because we were worried about the diameter of the saphenous vein, and that's why we took... we have that language up on the board, and we think that... out of that very concern.

Kevin Walsh: Can we see on the screen the language of the decision.

Josh Morse: Yes.

Gregory Brown: One way of approaching it would just be to include [inaudible] tributary varicosity could all be [inaudible].

Chris Standaert: You know, it would almost read differently if you took out the line that says all [inaudible] indications and you went [inaudible] reflux in the affected vein and a minimum of three months of pain or symptoms, right, and then you put the third line for tributary [inaudible], the diameter must be greater than or equal to 3 mm. So, the first, the second and third become the first two, and there's an 'and' in between them, and the third one is not an and. It's just [inaudible] you would just leave [inaudible] or tributary varicosities, the diameter must be greater than or equal to 3 mm, and then, I believe, we had gotten back to just treating a more inclusive definition of varicose veins. [inaudible]?

Joann Elmore: It does. That sounds fine.

Carson Odegard: This is Carson. I would agree with that.

Laurie Mischley: This is Laurie. I like that.

Kevin Walsh: I'm a little confused. So, the proposition would be that tributary varicose veins greater than 3 mm do not have

[inaudible] or have symptoms for more than three months. They just [crosstalk].

Chris Standaert: No. No. I would switch it. So, we're going to [inaudible]. So, under indications, so I... I might be looking at the wrong document for this thing, but it says indication, you take out the words 'are required to be present.' I guess you would leave it all. Well, I mean, you can't pull all, yeah. So, take out the all, required to be present with indication from the first line demonstrated reflux in the affected vein, and minimum of three months of symptoms, pain, and/or swelling, that doesn't interfere with instrumental ADLs or the presence of complications. Then you put a third one would say for tributary varicosities, the above two conditions multiply and the veins must have a diameter greater than or equal to 3 mm. So, that includes those first two things. You can't [inaudible] reflux or whatever, but fill that in. Those conditions apply to the tributary varicosities, but tributary varicosities does not become a limitation of the veins that you can treat. Is there a way to put that language up somehow?

Christine Masters: Are you not seeing it?

Chris Standaert: Oh, there it is. OK.

Christine Masters: OK.

Chris Standaert: OK. I'm sorry. I was looking at a different [inaudible] separate document. OK. Must include the above.

Laurie Mischley: [inaudible] by the end of the first two a big AND, and then before the third bullet should be IF a tributary varicose vein.

Chris Standaert: I would put for tributary varicose veins, or comma.

Christine Masters: Where'd it go? Hold on.

Chris Standaert: The above two conditions...

Christine Masters: I got it.

Chris Standaert: . . . the above two conditions multiply.

Joann Elmore: [inaudible] AND, the above two conditions multiply AND...

- Chris Standaert: AND, then let's have the diameter greater than or equal to 3 mm.
- Gregory Brown: Can we go back now real quickly to see the [inaudible]?
- Christine Masters: Yes.
- Josh Morse: Are you able to see it?
- Gregory Brown: No.
- Christine Masters: I don't know why it hasn't updated. Let's see.
- Gregory Brown: Josh, maybe you could just read the [inaudible]? Thank you.
- Chris Standaert: [inaudible] truncal saphenous veins, as it pertains to thermal ablation.
- Gregory Brown: I'm sorry, but I'm confused, because I still ferret out the intent of Dr. Ferris' statements. I understand [crosstalk].
- Chris Standaert: [crosstalk]
- Gregory Brown: I understand that the changes [inaudible] proposed are... bring clarity to our original language. So, I am supportive of that, too, because it's more clear in we're not limiting the tributaries [inaudible], but I still don't understand what this doctor has requested.
- Chris Standaert: Can you go back to our decision?
- Christine Masters: Yes.
- Chris Standaert: So, we're really not changing the language or the scope of our decision by altering the language. We're not changing the scope of our decision. We're just clarifying the objective of our language.
- Gregory Brown: I think it's better now.
- Chris Standaert: Yeah.
- Gregory Brown: Versus, yeah.
- Seth Schwartz: I agree.

- Chris Standaert: Yeah. OK.
- Male: My understanding of the letter is that Dr. Ferris is concerned that in the original language, perhaps, treatment for truncal varicosities would be not covered, but I think from... at least with the change in language that wouldn't be an issue.
- Chris Standaert: I agree.
- Seth Schwartz: I'll make a motion that we accept this revised language.
- Josh Morse: We do have one more comment.
- Christine Masters: Should we go back to that?
- Josh Morse: Chris?
- Chris Standaert: Yes, the other comment is from Medtronic.
- Christine Masters: Hold on.
- Chris Standaert: Asking that we clarify our contraindications, essentially, by using acute DVT instead of DVT, significant peripheral arterial disease instead of [inaudible] arterial disease, and active infection [inaudible] ulcer.
- Christine Masters: Whoa. There we go. It's [inaudible].
- Chris Standaert: Then, they requested that they review a particular device, brand and device next year. So, I don't know. I am not inclined to change some of the language on the exclusions, because we're getting [inaudible] some words here [inaudible] versus significant. [inaudible] define significant, right? We're allowing clinical discretion in here, and assuming somebody wouldn't be doing this [inaudible] procedure if somebody was [inaudible] I think is reasonable to assume. They wouldn't be doing that, but [inaudible]. I think we're, I don't know. I don't know how other people feel about it. I would allow some clinical discretion on this part, though.
- Joann Elmore: This is Joann. I agree with you Chris. I [inaudible] people in [inaudible] indication for [inaudible] arterial disease, but I'm fine with leaving things the way they are.

- Chris Standaert: Any other suggestions for changing or responding to the language otherwise in our decision?
- Kevin Walsh: I agree with Joann and with you [inaudible].
- Chris Standaert: OK. Alright. So, do we carry the motion to approve our amended, our current version of clarifications? Can we pull that back up again, please?
- Christine Masters: Yes.
- Gregory Brown: Hi. This is Greg. Sorry. I was in surgery this morning.
- Chris Standaert: You're off saving people.
- Gregory Brown: I've got a thing for hip arthritis.
- Chris Standaert: There we go. The only thing I would do on this last one that you have done is [inaudible] multiply put and they must have a diameter, I would just say must, put and they must have a diameter [inaudible]. Questions, comments, or motion to approve. [inaudible] Did we get a motion to approve, Josh?
- Female: Yes.
- Chris Standaert: Sorry. Any more comments or comments or discussion or we'll go to a vote? [inaudible] roll call.
- Josh Morse: If you approve, please say approve. If you disapprove, say you don't, and if you abstain, please say you abstain. Dr. Brown?
- Josh Morse: Brown?
- Gregory Brown: Approve.
- Josh Morse: Elmore?
- Joann Elmore: Approve.
- Josh Morse: Hearne?
- Chris Hearne: Approve.
- Josh Morse: Mischley?

Laurie Mischley: Approve.

Josh Morse: Odegard?

Carson Odegard: Approve.

Josh Morse: Schwartz?

Seth Schwartz: Approve.

Josh Morse: Standaert?

Chris Standaert: Approve.

Josh Morse: Walsh?

Kevin Walsh: Approve.

Josh Morse: Rege?

Sheila Rege: Approve.

Josh Morse: Yen?

Tony Yen: Approve.

Josh Morse: And Bramhall?

John Bramhall: Approve.

Josh Morse: Thank you. All approved.

Chris Standaert: We'll move to our second decision on [inaudible].

Christine Masters: Mm-hmm. Let's see.

Chris Standaert: And migraines. [inaudible] migraine part? [inaudible] chronic migraine and tension type headache is what we talked about. So, we received one comment on our decision from Dr. Johnson who brought up several issues with our decision. One was the definition of chronic migraine, because if we use the [inaudible] definition [inaudible] definition, then our decision [inaudible]. So, it lets our language be flexible over time and is more specific and more [inaudible] people can find the [inaudible]. The

second issue is the discontinuation criteria, which is a bit of an issue, and the maximum treatment cycle. So, if injection will work [inaudible] backwards, but the way number two reads implies that if the injection works and [inaudible] treatment. I don't think that was our intent. Then she asked, well, what do you do after five treatment cycles, and where did that come from? That number came from the actual study, the [inaudible] studies that we looked at, the treatment profile of the cycle, and we're not... as far as I know, we don't have treatment beyond that. Then, she asked about the word manipulation [inaudible]. [inaudible] 50% reduction in headache days [inaudible]. Yeah. So, no. She said our [inaudible] has shown inadequate response to treatment defined as less than 50% reduction in headache days, and she wanted that to be greater, but the thing is, that becomes a [inaudible] wrong way. I think this is the correct way, inadequate response due to [inaudible] 50% reduction. [inaudible] not a greater than 50% reduction. I think our language is correct there. I have no problem changing our definition of migraine, chronic migraine, as [inaudible] as defined by the International Headache Society. [inaudible] people can use whatever their definition may be at the time. And then we have the five treatment cycle issue. Other comments about her, Dr. Johnson's suggestions or comments to us?

Gregory Brown: I agree [inaudible] evolve over time. Then, we picked five, because that's what the studies showed and then, I think that's where the evidence is, and that's what we're bound by.

Chris Standaert: Then [inaudible] expert was saying that ideally isn't just you do botox and you leave people alone. You do botox as part of a broader intervention on their chronic migraine. That's what the intent of the study and the intent of the treatment was [inaudible] using botox, but I don't know that we have [inaudible] for botox over ten years. We don't have that. Other comments on [inaudible]?

Laurie Mischley: This is Laurie. I agree with everything that you're saying. The only place I'm getting a little hung up on is the five treatment cycles. I mean, we approve things all the time and the study period is shorter than the intended use in real life. So, because the study only goes... people are prescribed for 20 years, but the study hasn't necessarily gone 20 years. So, just being thoughtful about... I, I think

the decision was made based on our expert saying, again, in reality people don't keep going back for botox. It hurts. It's not looking as something we use repeatedly. So, I think that's where, because the studies have only gone on for five cycles and our expert said in reality, people don't... it's not a repeatedly used therapy. We did that, but I don't know that that is a good enough reason to say if it's working for somebody and they do want to continue it, they shouldn't be allowed to.

Gregory Brown: With the way it's worded for five and they believed the [inaudible] and for higher ones who come back for another treatment [inaudible] then just [inaudible] include any Health Care Authority or any [inaudible] treatment.

Chris Standaert: I don't know. I wondered about a line of [inaudible] review for treatment beyond five cycles or something. I don't know if we can put that in there or not. I agree. I don't know that I want to [inaudible]. I think the number of people will be small, but if it's [inaudible] if there are no other treatment options for them, but at the same time, we don't know, you know, [inaudible] doing this forever and ever and ever. People are funny. They [inaudible] things change, then you [inaudible] for years. We don't have any idea of the long-term efficacy, of the [inaudible]. So, if we leave it as is [inaudible] five cycles and still find they have persisting migraines once they stop that, can they, does our language exclude them from [inaudible]?

Josh Morse: It depends.

Chris Standaert: On what?

Josh Morse: I think the answer is yes, it may exclude them from receiving more, but I think that your answer is [inaudible]. So, my recall of this was that a cycle was three or four months. Is that right? So, you'd be looking at a year to a year and a half?

Chris Standaert: Mm-hmm. Yeah.

Josh Morse: Or more. Yeah. So, I think if you have a maximum of five treatment cycles, you're applying a limit that it could likely be applied.

- Chris Standaert: Are we allowed to put a line in saying... [inaudible] may apply for repeat treatment cycles beyond five or repeating them? Like, I don't know what that looks like [inaudible] ten years later on they'll do it again. Are we giving them a lifetime ban or can we put in language that [inaudible] that doesn't let people just sort of do this forever without stopping. Rather than doing five treatment cycles and seeing that somebody has responded and longer-term to the treatment, um, but that was still [inaudible] be to review it at the end. Sort of re-enter the five [inaudible].
- Sheila Rege: Yeah. So, on the Medicare line. This is Sheila. So, on the Medicare line which says usually five treatments and then kind of more than five treatments may be subject to preauthorization or something like that, and I wonder if we can do something like that?
- Chris Standaert: Yeah. That's what I'm wondering. Can we use language like that, Josh?
- Josh Morse: [inaudible] or did you say more may be approved, or?
- Chris Standaert: So, after the maximum five treatments, can we put consideration of additional treatment cycles would be up to each individual agency's review.
- Josh Morse: Yes. You could say that. Agency discretion or something like that.
- Chris Standaert: OK. So, then they can figure out for these people what their criteria for repeat cycle is and make sure people are doing what they're supposed to be doing to consider other options.
- Josh Morse: Yes. I wonder...
- Chris Standaert: We don't have to deal with addressing it [inaudible]?
- Josh Morse: The word episode comes to mind, but that might not be the right word. I mean, if you're, I mean, you know, two years later your migraine returns and it's a new episode, is there language like that you could apply?
- Chris Standaert: That's what I'm trying to, right. That's what I'm trying to get at is, can you, either you think of this as a five-treatment cycle intervention, it's a year and a half long intervention,

can you redo it if people, if the condition recurs, or if that appears to be the only effective treatment for this condition and so on the remaining as a long-term chronic condition. We don't have data on that, but we could let the agency figure that out with the individual circumstance.

Joann Elmore: This is Joann. Could we pull up the draft by [inaudible] decision, editing it. I think that's good, because I can always [inaudible] and I may need to go pretty soon. Thank you.

Chris Standaert: Can you put a line up [inaudible] additional treatment may be considered at agency discretion. [inaudible]

Josh Morse: Yes. You can say that.

Chris Standaert: Does that help, do people think, or do we not need that?

Gregory Brown: Could we add the language based on available evidence? [inaudible].

Seth Schwartz: I think if we're going to leave it, we can leave it up to the agency. They can decide how they want to do it.

Sheila Rege: I would agree. [inaudible]

Carson Odegard: I agree. Well, it doesn't it so if somebody wants to do more than five they [inaudible] dealing with the agency [inaudible] defining what they're doing, which seems reasonable. I don't know.

Joann Elmore: This is Joann. Going beyond five is beyond any existing evidence, and I would appreciate maybe in a future meeting if Josh could clarify, we have been told in the past our committee has been told that if anyone wants an exception, even if we have listed inclusions and exclusion criteria that they could simply talk with the agency medical director. So, I don't understand why we need to add this caveat.

Chris Standaert: That isn't so much. If our decision is sort of final, if we put a cap, that is it. They can consider use under a research protocol, but they can't just expand coverage, should they [inaudible].

Joann Elmore: Could they be...

Chris Standaert: Yeah. So, if they were to decide, somebody wanted to come and said I want to research ten cycles, then they can say sure. We'll cover that as part of your research protocol, but they can't just decide on their own, well, they're gonna make the yeah. So, if this person wants more, we'll just give them more. They can't do that, as far as I know. Josh, am I interpreting that correctly?

Josh Morse: Yes. You are.

Chris Standaert: Yeah. So, you could take our original decision as saying, five treatment cycles is all you get for the rest of your life. Christine, or whoever is typing, can you change for treatment of chronic migraine as a parenthesis just put as assigned by [inaudible]?

Josh Morse: Yes.

Gary Franklin: Josh, can I point something out?

Josh Morse: Yeah.

Chris Standaert: Yeah, that's you, Gary?

Gary Franklin: Yeah. The reason we wanted to put that in there is that there, the [inaudible] by definition is more than just the 15 days and the eight days of migraine. It also includes [inaudible] defined migraine has been transformed from regular migraine, and if there's a history of regular migraine and if, you know, I think if botox is successful in this, somebody could revert to regular migraine. They would just get regular treatment for that. So, that's why we wanted to put this in here. Number one, to make sure that they actually had migraine, real migraine, you know, regular migraine and the number of days, which was already in there.

Chris Standaert: I think we need to [inaudible]. You've got the [inaudible] for clarification [inaudible].

Josh Morse: So, does the language reflect that now, Chris?

Chris Standaert: Huh?

Josh Morse: Does the language...

Chris Standaert: I think that wordage [inaudible].

Josh Morse: OK. You're going to see what [inaudible] is written?

Chris Standaert: Yeah.

Gary Franklin: Yeah. It's fine.

Josh Morse: OK. Thank you.

Chris Standaert: Other questions or comments or a motion to approve?

Seth Schwartz: This is Seth. I move to approve.

Chris Standaert: And a second.

Carson Odegard: Second. Second, Carson.

Laurie Mischley: Second.

Josh Morse: OK. We'll do a...

Chris Standaert: Any more discussion or we'll go through a roll call? Go through the roll call then?

Josh Morse: Alright. Dr. Brown?

Gregory Brown: Sorry, I approve.

Josh Morse: OK, Elmore?

Joann Elmore: Oh, I vote to not cover, but I approve the edits.

Josh Morse: Thank you. Dr. Hearne?

Chris Hearne: Approve.

Josh Morse: Mischley?

Laurie Mischley: Approve.

Josh Morse: Odegard?

Carson Odegard: Approve.

Josh Morse: Schwartz?

Seth Schwartz: Approve.

Josh Morse: Standaert?

Chris Standaert: Approve.

Josh Morse: Walsh?

Kevin Walsh: Approve.

Josh Morse: Rege?

Sheila Rege: Approve.

Josh Morse: Yen?

Tony Yen: Approve.

Josh Morse: Bramhall?

John Bramhall: Approve.

Josh Morse: OK. That's all approved. Thank you.

Chris Standaert: We are done, yeah.

Josh Morse: We are done. Thank you, again, Dr. Odegard. This is his last meeting.

Chris Standaert: Thank you, Carson.

Carson Odegard: Yeah. Thank you very much.

Josh Morse: And Chris, as well.

Carson Odegard: It's been an honor.

Chris Standaert: It's been an honor.

Gary Franklin: Chris? This is Gary. I couldn't [inaudible] Pennsylvania and Googled [inaudible].

Josh Morse: Thank you all very much.