Washington State Health Care Authority

Washington State Health Technology Clinical Committee Meeting

Hyperbaric oxygen therapy for sudden sensorineural hearing loss and continuous glucose monitoring

March 21, 2025

Josh Morse

Everyone on this Zoom here and now the recording has started.

Janna Friedly

Great. Well, thank you everybody for joining this this morning. Josh, do we, do we have. Looks like we have some folks. I don't know that we have quorum to get started, do we?

Val Hamann

No, we do not.

Josh Morse

We're getting close. I will get the agenda.

Janna Friedly

Which other, can you remind me which other committee members are we expecting that we're waiting for today?

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Val Hamann

Yeah, Amy just logged on. We have. Jonathan Staloff just logged on.

Amy Occhino

Good morning.

Janna Friedly

Hi, good morning. Thanks for joining. Good morning.

Josh Morse

I'm going to share the agenda briefly. And once we have a quorum, Janna, I think we can start with introductions and any disclosures that committee members has, and then I can give our brief standard presentation before we move into previous meeting business, if that works for you?

Janna Friedly

Sure. You wanted to go through introductions of the committee members today? Okay.

Val Hamann

And it looks like we are still waiting on Dr. Oakes this morning. But other than that, we have everybody who said that they will be attending.

Janna Friedly

Okay. Well, Josh, maybe we should just go ahead with the introductions while we're waiting for Dr. Oakes to join us.

Josh Morse

Okay. And Val, we do have a quorum then?

Val Hamann

Yes, we should have seven right now.

Josh Morse

Great. Okay.

Janna Friedly

Okay, great. And Tony, can I ask if you could serve as our timekeeper today to keep me on track for the meeting?

Tony Yen

Sure, I will do that.

Janna Friedly

Okay, thank you. I really appreciate that. Okay. So we'll go ahead and get started with introductions of the committee members and any disclosures related to these topics today. So I'm Janna Friedly. I'm a physiatrist professor at the University of Washington. I'm the chair of the committee and I have no disclosures, no new disclosures or disclosures related to the topics that we're discussing today. And I will pass it to Tony then.

Tony Yen

Hi, I'm Tony Yen. I'm a hospitalist at Evergreen Hospital. I'm also the CMIO over there I have no disclosures.

Janna Friedly

Okay. And then I see Amy is next on my screen.

Amy Occhino

Good morning. My name is Amy Occhino. I'm an OBGYN hospitalist at Sacred Heart Medical Center in Spokane. I'm also faculty at both of the Spokane campus medical schools and I have no disclosures.

Janna Friedly

Great. And Laurie.

Laurie Mischley

My name is Laurie Mischley. I'm a naturopathic doctor here in Seattle in private practice and do research at University of Washington and Bastyr University, and I have no disclosures.

Janna Friedly

Great. And John?

John Bramhall

Yes. Hi, good morning, John Brahl. I'm an anesthesiologist by training. I'm a professor at the University of Washington. I have no disclosures this morning.

Janna Friedly

And Jonathan.

Jonathan Staloff

Hi, I'm a family medicine physician at Harborview Medical Center and faculty at University of Washington. No disclosures.

Janna Friedly

And Chris?

Chris Hearne

My name is Chris Hearne. I'm a nurse practitioner. I work with Swedish Hospital Medicine in Seattle, and I have no disclosures.

Janna Friedly

And Evan.

Evan Oakes

Hey everybody, I'm Evan Oakes. I'm a board certified family physician and chief health officer for HealthPoint, serving King County and I have no disclosures.

Janna Friedly

Great. Thank you. Did I miss anyone?

Josh Morse

Dr. Rubinstein is our clinical expert this morning.

Janna Friedly

Okay, there we go. Great.

Jay Rubinstein

Hi, my name's Jay Rubinstein. I'm a professor of otolaryngology and bioengineering at UW and I'm the director of the Virginia Merrill Bloedel Hearing Research Center at the U.

Janna Friedly

Great. Thank you so much for joining us today. We really appreciate you being here and your expertise.

Jay Rubinstein

It's been.

Janna Friedly

Great. Okay, Josh, any other announcements before we get on to previous business?

Josh Morse

I'll do the brief presentation just on what's happening today at the meeting, and then we'll move to previous business. And it's going to take me just a second to get oriented here. Okay, it looks like the presentation isn't right sequence, right? Okay.

Okay, welcome this morning. This is the Health Technology Clinical Committee meeting on March 21st, 2025. I'm Josh Morse. I'm the Health Technology Assessment Program Director. We are recording this meeting, a transcript of the meeting will be available afterwards, you can see on here our website address you can find this on the Health Care Authority's web pages. We, um, the chat function is not technically disabled, but we really request that nobody use it, committee members, especially we, the chat is not a good tool for these virtual Zoom meetings so we are not using the chat function today. HTA program background. The Health Technology Assessment Program is administered by the Washington State Health Care Authority. The HTA program brings evidence reports to the Health Technology Clinical Committee to make coverage decisions for certain medical procedures and tests based on the available evidence for safety, efficacy, and cost effectiveness. Multiple state agencies are participating in this process and implement these decisions, and this includes the Health Care Authority representing the Uniform Medical Plan and the Apple Health Medicaid program, the Department of Labor and Industries, and the Department of Corrections does use the policies from this process. So these agencies and programs implement the determinations from the Health Technology Clinical Committee, each within their own statutory frameworks. So the purpose of this process is to ensure that medical treatments, devices, and services that are paid for with state health care dollars are safe and proven to work. This program provides resources for these agencies that are purchasing health care and through this process, we develop scientific evidence-based reports on the selected devices and tests that are reviewed by the HTCC. And our team supports the HTCC to make these determinations for the selected technologies. There are multiple ways to participate in this process and again, we have a website that is linked off of the Health Care Authority's website. Anyone may sign up to receive HTA program notifications by email and provide comment on topics that are proposed for review in this process, on key questions, on draft and final reports, on draft decisions, anyone may attend these public meetings and present comments directly to the committee, and anyone may nominate technologies for review or rereview.

Our agenda today, we've started, we've done introductions and disclosures, uh, we will move into previous meeting business after this presentation and look at the minutes from the January meeting and then comments on the vertebroplasty, kyphoplasty, and sacroplasty findings and decision. The committee will then vote on a final decision. And then we will have technology reviews today for hyperbaric oxygen therapy for sudden sensorineural hearing loss and then continuous glucose monitoring. We do have a public comment period for each of these topics. Time is limited. We will use

the hand raise function for people who have not signed up to comment prior to the meeting, instructions will be provided. We will, we ask that people limit comments to the time that is allotted and staff will monitor that time and indicate when it's up. For those that are attendees, you will be elevated to be allowed, be able to speak through the, the Zoom technology. It'll take a second for that to happen and then after your comments, that will change back. So people who are providing public comment, we ask to clearly state your name, declare any conflicts of interest, and then provide your comment within the allotted time. After today's meeting, our team will publish the approved minutes and transcripts resulting from the previous meetings and any draft determinations from the meeting. Draft determinations from today will be available for public comment for two weeks.

So our next scheduled meeting is June 13th, this is the frenotomy and frenectomy with breastfeeding support topic and then for September, we have scheduled balloon angioplasty and stenting for lower extremity peripheral arterial disease. So if you have questions, you can see our, our state health technology assessment program email address here and again, a reminder that we have a, a lot of this material is on our website. So that concludes our presentation. If committee members have questions for me, please let me know.

Janna Friedly

Thank you, Josh.

Josh Morse

You're welcome.

Janna Friedly

Okay, so let's move to previous business, uh, the first order of business is to approve the minutes from the last meeting and so I will, and these, all of these materials have been available to you to review. So I will need a motion to approve.

Tony Yen

I move to approve.

Janna Friedly

And a second?

Jonathan Staloff

Second.

Janna Friedly

Any discussion? Okay, and all those in favor Say yes.

Tony Yen

Yes, I.

Jonathan Staloff

Yes.

Laurie Mischley

Yes.

Chris Hearne

Yes.

John Bramhall

Yes.

Amy Occhino

Yes.

Janna Friedly

Great. Okay. So the minutes are approved from last the last meeting. The next order of business is reviewing our decision from the last meeting, which was vertebroplasty, kyphoplasty, and sacroplasty. And Josh has this up on the screen, as you will recall. We've gone through the processes outlined on this on the screen and at our last meeting, we came to a decision of no coverage. We had several letters, comments that have been submitted since the last meeting.

I will just, each of those letters, I think addressed similar issues and so just want to summarize briefly what those issues are for us to consider. Really, our task with this is to identify if there's new evidence that was presented in these comments that we did not consider or that would substantially change our decision that we would need to need to rereview our decision. The issues that were brought forward, there were a few that were procedural. One was around the amount of time that each of the clinical or each of the public commenters were allowed and for their comments and suggesting that was not the four minutes was not enough time to adequately present their concerns and that we did not incorporate enough of the public commenters in the discussions. There was another concern that we did not consider the LCDs versus the NCD when we were comparing our decision to existing guidelines and national decisions. And then the other major comments were around the incorporation of observational data, registry data, claims data rather than focusing on entirely on randomized controlled trials as we did in our report and so there was concern that we did not fully incorporate that evidence in our decision making. So I think those were the major themes in the, in the concerns. I'll just address the procedural issues first, and then I'll open it up to discussion about the evidence. We are required by law to, as part of the statute to consider Medicare national coverage decision and for this, there is no national coverage decision. There are local coverage decisions and so we as part of this, we do look at those, we look at other clinical guidelines from societies and, and other organizations and compare but we are, we are not required as a committee to necessarily have the same outcome or the same decision and there's many reasons why the our process is different and the evidence that we consider may be different than those so just want to make sure that people understand that. And then in terms of the time, there is we, and Josh can maybe speak to this a little bit more from the historical perspective, but we have allotted typically four minutes for the clinical or for the presentations for the public comments, because of that that's consistent with other similar committees including Medicare processes, and so when this committee was established, there was a scan done of other similar bodies to see what the precedent was and what the process should be. We have to be equitable and so when there are many different public commenters, which there are sometimes for these topics that are of particular interest, we, we have to have some equitable way to ensure that people get equal time and we have to have some sort of limit, so four minutes is what we have historically done for all of our public comments. We do, of course, have the slides and the available and we all review those and incorporate those into our decision making as well. I just wanted to make sure that people were aware of how we do things. From my reading of the letters and evidence that was presented, I did not see any new evidence presented that we did not consider in our discussions and in the evidence that was presented by the public commenters. But I would appreciate any comments from the group about the public comments.

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John Bramhall

Janna, I'll just say it's this we've had complaints before about the three or four minute restriction. I agree. It's not a long time, but I think people complaining if they went to Olympia, they'd find they get 90 seconds sometimes never more than two minutes to make a comment about legislation that's relevant to their to their work. So like you say, it's fairly standard. It's not perfect, but we're not here to listen to a lot of rhetoric from people who have a preordained view on something, we're here to analyze the literature as objectively as we can.

This letters, the both letters, they're articulate, they're very, very conventional complaints that we often hear in particular with procedures that are related to spine manipulation and reconstruction and what have you. It seems to bring out a lot of energy and I understand part of the reason for that. The letter, two things were amusing to me. I'm using the wrong word. Curious. One is that Dr. Beal's letter complains that we looked at some older literature in particular, the Shan trials, which, as I recall, were I mean, these were big pieces of information that helped guide our, um our decision, I think. And the complaint is, well, we're looking at old data. Well, it's not that long ago, Josh, that we had a complaint in exactly the opposite vein that, that we considered when we were re-reviewing only new material and that we should emphatically re-review the older literature so I you know we're not going to win that. I think what we did in this case was entirely appropriate. We had a very large data set that was analyzed by a professional team of, of people, the data analytics. We went through it as carefully as we could and there was no evidence in the literature that supported us saying that this kind of plastic technique was any better than sham so that was our decision. And the only other comment was this weird little thing they picked up on and it was my question. That's why I mentioned it. I wondered aloud whether the balloon kyphoplasty was this a mechanism by which you could insert resin, you know, acrylamide paste without a fear of embolization, which is a significant concern and I personally have been involved in cases where embolization has had dramatic results and our clinical expert, I think, was present at one of those many years ago. So it was something I thought about. And I asked the question openly and got an open answer. And so Dr. Beal seems to suggest that this was an ignorance on the part of the committee to a misunderstanding of how this all works. And no, it isn't and no, it wasn't. That's all I'd have to say.

Janna Friedly

Okay, thank you. And this is obviously a very challenging topic and clearly as you all know, we did not have, you know, it was not a unanimous decision, which always suggests that there's some mixed evidence. And so, um, I really appreciated the thorough discussion that we had about the evidence. Are there any other Comments?

Tony Yen

Hey Janna, just my timekeeping duties over here.

Janna Friedly

Thank you. We are. Great. So unless there are any other comments about this. Josh, I think we at this point need to move to a final, final vote is that the next step.

Josh Morse

That is correct. I think Val will manage the vote on this when you're ready to. So for you is the draft determination and this is what you will be voting for or voting on, I should say.

Val Hamann

Yeah, so we do not have a poll for this one. I will just go down the names so please let me know if you approve to this draft findings. So John Bramhall.

John Bramhall

Yes, I approve our original decision.

Val Hamann

Janna Friedley.

Janna Friedly

Approve.

Val Hamann

Chris Hearne.

Chris Hearne

Approve.

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Val Hamann

Laurie Mischley.

Laurie Mischley

Approve.

Val Hamann

Evan Oakes.

Evan Oakes

Approve.

Val Hamann

Amy Occhino.

Amy Occhino

Approve.

Val Hamann

Jonathan Staloff.

Jonathan Staloff

Approve.

Val Hamann

Tony Yen.

Tony Yen

Approve.

Val Hamann

So we have eight to approve.

Josh Morse

Thank you, Val. Okay, that concludes our previous meeting business.

Janna Friedly

Only four minutes behind. Schedule.

Josh Morse

Doing great. Thank you.

Janna Friedly

Okay, let's move on to our topic. Hyperbaric oxygen therapy.

Judy Zerzan-Thul

Okay. Hello, everyone. Good morning. I'm Judy Zerzan-Thul. I'm the Chief Medical Officer here at HCA. And I'm excited to present to you about sudden sensorineural hearing loss and, uh, that was some tap dancing waiting for the slides. Do you have the slides? Am I supposed to have the slides?

Val Hamann

Either way, what.

Judy Zerzan-Thul

I would love it if you had the slides.

Val Hamann

Perfect.

Judy Zerzan-Thul

Because I did not save the most recent version.

Val Hamann

No problem.

Judy Zerzan-Thul

I'd have to dig it up. Yes. So I'll just start talking. Sudden sensorineural hearing loss is a rapid loss of hearing over a short period of time, usually within 72 hours, and involves a decrease in hearing of about 30 decibels or more. 30 decibels is about the difference where you can't hear whispering or you can't tell the difference between D and G. And things like that. And it has to affect at least three different frequencies. The next slide, please. And there were about 66,000 cases diagnosed per year so it is relatively rare disease. And almost all the cases are idiopathic and somewhere between one third and two thirds of cases recover spontaneously, which really complicates looking at treatments and where, where that goes. Today, we're also going to be including acute acoustic trauma, which is a subset and a less common cause of SSNHL. This is mostly caused by firearms near the ears and is seen a lot in the military population.

So. Hyperbaric oxygen therapy involves the therapeutic administration of 100% oxygen at environmental pressures above one atmosphere absolute or ATA is the, the units that are given and one ATA is the atmospheric pressure at sea level. And it's thought that vascular compromise and in particular cochlear ischemia is a potential etiology of idiopathic sensorineural hearing loss. And so because the direct vascular supply to the cochlea is actually quite limited, but there are high oxygen needs and so it's thought that the increased partial pressure of oxygen from the HBOT allows for delivery of more oxygen and improves microcirculation and then, and then fixes it. There are 15 HBOT centers, hyperbaric oxygen treatment centers in Washington. They're all in the western half of the state and mostly the northwestern half of the state. Next slide. So our current agency policies, it is non-covered and considered not medically necessary by the 2013 HTCC decision, and that affects PEBB and SEBB, Apple

Health, and Labor and Industries. At that time, the committee found low certainty of evidence due to mixed results from the eight randomized trials that were reviewed that were all within two weeks onset of hearing loss. And the findings were inconclusive as to whether there was a benefit in the acute phase.

There was a moderate certainty of evidence that there could be, but overall suggested no benefit.

Next slide. So why are we here today? There are a number of new studies that we'll look at, two of the studies were reviewed before, they're older, but also the FDA who regulates both the oxygen and the hyperbaric chambers approved HBOT for use of sudden idiopathic hearing loss and you'll see what the literature suggests we might want to change our view. So it's worth a look. Next slide. The agency medical director concerns for safety was medium, efficacy was high, and for cost was medium. Next slide. So these are the diagnosis and procedure codes. There's nothing super exciting there. Next slide. And here is the utilization and cost. It is used very low and actually, these utilization includes a sort of undifferentiated hearing loss use, which may not actually be sudden sensorineural hearing loss but in order to get enough encounters that we can share some data with you, we included it and we looked over four years of data. So there were 13 individuals that had a total of 252 treatments with HBOT and the average paid per case was about $5,000. Next slide. So looking at other payers policies are really all over the map. And so this is sort of put into a spectrum of covered to who knows. But so the top three, Humana, Premera, and United, I'll cover it then we get a little more specific into policies. Aetna covers it within three months of onset, Cigna within four week, Kaiser within two weeks if possible, six weeks at the most, Regence covers it for a greater than 40 decibel hearing loss and with 14 days of onset and then TRICARE and CMS have no policy about it.

Next slide. So there are four organizations with treatment guidelines around HBOT. NICE actually doesn't mention this indication for hyperbaric treatment, but three of the entities that do suggest covering. So the American Academy of Otolaryngology and the European Committee for Hyperbaric Medicine recommend HBOT as an option for the treatment of sudden sensorineural hearing loss when combined with medical therapy in patients who present within two weeks of hearing loss and no later than one month. And then the Underseas Hyperbaric Medical Society says to consider HBOT for patients with moderate to profound hearing loss who present within 14 days of symptom onset. Next slide.

These are our key questions. Is HBOT effective in this condition? Is there differential effectiveness and safety? Are there harms and what is the cost effectiveness? Next slide. And I'm going to start with giving you sort of an overview of the studies, because in general, the studies were very small with sample sizes ranging from 25 to 121 participants at most, which reflects this isn't a common condition. None of the trials were in the United States. The specific steroid treatments used either as co-interventions or as comparators, the dose and delivery route was different. Some had oral steroids, some IV, some injected

into the tympanic membrane steroids, so really a number of things. The timing of the HBOT treatment after the symptoms varied and the definitions of hearing recovery varied across studies, and most didn't define what degree of hearing recovery was clinically meaningful. And so all of this sort of limits the statistical power and the precisions of the effects. However, despite laying these like, look carefully at the studies, it does seem like there could be a signal of effectiveness. So next slide. The, you'll see in the review that there is an analysis and pooling of data that comes up with an absolute risk difference of 180 more people per thousand that achieve complete or partial hearing recovery with HBOT compared to steroids alone and there's a pretty big confidence interval there, but it still is all positive. There are 10 randomized studies that you'll hear about later that show folks with HBOT plus steroids are about 40% more likely to achieve complete or partial recovery compared to those treated with steroids alone. And then looking at timing, that data is a little messy. So among the seven RCTs that compared HBOT with steroids to steroids alone as a treatment. Four of them reported differential effectiveness outcomes. One found that people treated within seven days had significant hearing recovery, but after seven days, they did not. One RCT found that hearing improvements were better among those that had a more severe hearing loss. But a second RCT in this group found no difference in the amount of hearing loss at baseline and treatment loss or treatment after 14 days was not effective.

Next slide. Although that was based on a very small sample. So looking at other ways of delivering the HBOT treatment, there is one RCT that compares two HBOT sessions per day for five days with one HBOT session per day for 10 days, so the same amount of treatment, just a different time period and found no significant differences. There's another study that compared early HBOT treatment, which they defined as within 10 days of loss of hearing versus late. And they define that as 11 to 30 days. And at six weeks, they found no statistically significant difference in hearing recovery between those two groups.

Another study looked at whether higher pressure worked. I will note the 1.5 atmosphere is not a usual considered effective dose in hyperbaric oxygen therapy. And so the higher pressure worked better and that perhaps is not surprising since the 1.5 is not usually used and increasing the time for that lower atmospheric pressure did not result in a significant difference. And then there is very limited evidence in any of these studies for differential effectiveness in terms of subpopulation, age, race, sex, disability, comorbidities, severity of hearing loss. I think there's not really much to say about that.

Next slide. So taking a dive into the acute acoustic trauma, which is treated separately in the report, as you saw, there are seven studies about acute acoustic trauma, mostly conducted in Europe among male military participants. One study was a randomized controlled trial and six were non-randomized. Two were before 2013, those were both done in Turkey, with one of them being from 1985, so quite old. And the single RCT is listed as high risk of bias because there is lack of information about baseline differences and allocation concealment and there are concerns about outcome selection and the lack of blinding for the outcome. And then the non-randomized trials are either serious or critical risk of bias because there is either no attempt or very poor attempts to control for confounding. There was also in these studies a lot of heterogeneity in terms of baseline hearing loss measured outcomes and the definition of recovery.

And so there wasn't a way to try and put these studies together to see if there was a signal of effectiveness there.

Next slide. So there are very few minor harms with HBOT treatments for sudden sensorineural hearing loss. Ear pain is the only one that's there that is not a long-term thing, but more of an acute thing. I suppose we talked about this a little bit, there are some even fatalities that happen in hyperbaric oxygen chambers, but those are very rare and I think not really not really needed to include here, this is a pretty safe therapy. And there were no studies on cost effectiveness. So our recommendations are that even though some of these studies are a little squishy, the preponderance of the newer studies appears to have some effectiveness. And so we are recommending coverage with, of HBOT with conditions for idiopathic sudden sensorineural hearing loss, for people that have moderate to severe hearing loss, that they start treatment within 14 days of onset of the hearing loss, and that steroids are also include in that treatment. And then we recommend not covering for acute acoustic trauma. And that is all. Are there any questions? Okay, this is sort of a very focused report. It was like, oh, here it is. So it's handy for a day that you have two decisions. Jay?

Jay Rubinstein

Yeah, was any effort put into looking at the under the data supporting the underlying pathophysiologic hypothesis for this treatment?

Judy Zerzan-Thul

Oh, not that I read about. I don't know. Do you know of any? It seems a little bit hand wavy.

Jay Rubinstein

I do, but we can discuss that when people ask me my opinion about this.

Judy Zerzan-Thul

Okay, that sounds great.

Janna Friedly

Well, now you've peaked our curiosity. You might as well tell us.

Judy Zerzan-Thul

Yes.

Jay Rubinstein

Okay, so usually when you have, you know, clinicians advising a panel like this, the clinicians are biased towards treatment. Here you have the opposite situation. I've never actually referred a patient for hyperbaric oxygen therapy, despite the fact that the American Academy of Otolaryngology puts it in their clinical practice guideline. And the reason I don't is I'm highly skeptical of the underlying pathophysiology for this disorder. The best evidence of several lines of thinking that are associated with this. One of them is that the best evidence we have for the pathophysiology of sudden sensorineural hearing loss is from cadaveric temporal bone specimens from people who died of unrelated disorders In the immediate aftermath of having an episode of sudden sensorineural hearing loss and there's zero evidence of ischemia and it appears to be an inflammatory lesion of the inner ear. And there's a lot of arguments. The leading hypothesis for many years is that it represented a viral cochleitis, but in fact, the fairly minimal evidence for virus, there's just evidence of inflammatory response. So that's concern number one. When you have an acidic cochlea, there are very specific histopathologic changes that occur.

And those have not been present in temporal bones from people who've had sudden sensorineural hearing loss during life. The second issue is one of the vascular supply. So it was mentioned that the vascular supply to the inner ear is tenuous and that's true it's a tiny little vessel the labyrinthine artery that is an end artery. But the end of the artery is in the low frequency part of the cochlea.

So one would expect that in sudden hearing loss, you'd get low frequency hearing loss much more commonly than high frequency hearing loss because the high frequency part of the cochlea is more proximal on this end vessel. And the reality is the opposite high frequency hearing loss is much more common than low frequency hearing loss in sudden sensorineural hearing loss. In addition, because it's the same vessel that goes to the vestibular system as goes to the cochlea, the branches to the vestibular system branch off of the vessel before the end vessel goes to the cochlea, one would expect much more commonly to have sudden sensorineural hearing loss associated with vertigo.

And in fact, while that does occur it's much more common to have sudden sensorineural hearing loss without vertigo, i.e., it's an isolated hearing loss. And when you have an ischemic cochlea in situations where we know there's actual cochlear ischemia it's profound deafness and it does not recover like

sudden sensorineural hearing loss commonly does as was also mentioned earlier. So to me, the whole logic behind hyperbaric oxygen treatment just makes no sense. Now, we have seen the RCT data and I don't suggest that I have a way of explaining the RCT data that's been seen except to say that as you all saw it's kind of all over the map in a lot of different ways. So that's my that's my take on this. As far as injury is concerned, we actually do see barotrauma from hyperbaric oxygen, it's not very common, but we do see it. And there are patients receiving hyperbaric oxygen treatment for a variety of causes that need to have myringotomy tubes placed in order to be able to tolerate hyperbaric oxygen. So it's not quite as, you know, quite as risk-free as was presented, but I agree, it's not a high risk intervention. I'm just still very, very skeptical that it has the effects that are suggested by the RCTs.

Janna Friedly

Great. Thank you so much for that, that information. I appreciate it. Any questions from the committee for Judy, before we move to public comment? John, did you? Okay. Great. Well, thank you, Judy. So I think we'll move to the public comment. And Josh, if I recall, we have one, one person scheduled?

Josh Morse

I believe I have one person signed up. Is that correct, Val?

Val Hamann

Yes, and they do appear to be present so I will promote them to panelists and then if we have any others in the attendees who are here and would like to speak on HBOT for either sensorineural hearing loss or acute acoustic trauma, please raise your hand at this time. Okay, I see Ty Jones. And Debra, you will have four minutes today. Feel free to start whenever you would like and I will give you a heads up at one minute, when you have one minute left.

Debra Quinn

All right. Thank you. Good morning, everyone. My name is Debra Quinn.

I am here today because on July 4th of July 2023, I went to sleep. I was perfectly fine. My hearing was perfectly fine. The morning of July 5th, I woke up and I was unable to hear, um, the same. I could tell that my hearing had been impacted. I went to urgent care that day. I was told to take Flonase and let them know if things improved a week later. Things did not improve. And on July 12th, I was diagnosed with SSNHL. The ENT, I saw an ENT, the ENT told me that the condition was rare and that the treatments for the condition included prednisone, steroid shots through the ear and hyperbaric chamber oxygen

therapy or HBO. I was also told that unless I began treatment within two weeks of onset for the HBO that there was a reducing possibility that my hearing would improve. I went to the local HBO facility where I live in, which is located in Vancouver, Washington at Peace Health. I met with them on July 14th and I was told I could start treatment the next week after my insurance authorized that, which would have been through this group. On July 18th, I'm a state employee, I was notified that Regence denied coverage based on HCA's 2013 findings and conclusions on HBO for SSNHL. I discussed this with my doctors who stated that was outdated information. I tried to contact Regence who told me to file an appeal, but they also told me that if I filed an appeal that it may prevent me from the ability to have a peer to peer review, which would have been a quicker process with the my healthcare provider. I tried to see if there was something I could do with the HCA opinion. The only thing I saw was an appeal form, so I filled that out, emailed it in. I asked the HBO if they would be willing to agree to request a peer to peer, which they did agree to do so. Regence also agreed to participate in that process and that was scheduled to occur on July 20, either the 21st or the 24th, I can't remember. I also asked my ENT to provide the HBO doctor with updated science to prepare for the peer to peer, which my doctor did. And then on, I was later notified by the HBO Center that Regence canceled the peer-to-peer and refused to consider reconsider their decision to deny the treatment. And as you can imagine.

Val Hamann

One minute remaining.

Debra Quinn

As you can imagine, given what I was initially told by my doctor that unless I engaged in the HBOT within two weeks, I would not have an ability to improve my hearing, I went into panic. I sent an urgent email to this group, HCA, telling my story, I luckily my email was read I just went to your website and found any name I could find. I found a nurse who read my email, she gathered a team of doctors that day and called me to tell me that the decision to deny the HBO was reversed. I started the HBO on the 24th of July. I went through two months of HBO treatment. My doctor did advise me that my hearing had improved after I had completed the HBO process. So I would, I would argue and urge you to please support coverage of HBO for SSNHL and also to have that coverage be allowed to commence within the 14 day period of diagnosis. Thank you.

Val Hamann

Thank you for your comments today. I will put you back as an attendee and I will be promoting Ty Jones.

Josh Morse

And I failed to ask. We asked public commenters to please disclose if anybody paid for you to be here today or paid for any travel. We're not in person, so that's probably moot today.

Debra Quinn

No.

Josh Morse

Thank you so much for taking the time to comment today. It's really appreciated.

Debra Quinn

Sure. Thank you for hearing me.

Val Hamann

Great. And feel free to take over Dr. Jones when you're ready.

Ty Jones

Good morning. Can you hear me? Oh, yeah, I see me too. Good morning. I'm Dr. Jones from Regence. I'm a medical director supporting the Washington State Health Care Authority account. As a reminder, Regence serves as the administrator of HTCC determinations for Washington's Uniform Medical Plan members. So you just heard from Debra, I'm assuming one of those members. Our coverage includes state workers, K through 12 school employees and their retirees. I'd like to share some additional relevant data from last year. So among our 450,000 Uniform Medical Plan members, we received just three requests for HBO therapy to treat sudden sensorineural hearing loss in the last year. The key point I wanted to emphasize is this, given such low request volumes, providing coverage for this treatment would likely have minimal impact to the state's budget while offering an evidence-based potentially curative measure to those facing acute and often significant hearing loss. Thank you for your time.

Val Hamann

Great. Thank you so much. Do we have any other participants in the attendees that wish to speak on HBOT today. I am not seeing anybody else.

Janna Friedly

Great. Okay. Well, thank you for those public comments. And I think at this time we can move to the evidence report.

Sara Kennedy

Just bring up the presentation for the evidence report. Are you all able to see my screen? All right. Well, some of this was already covered in the previous report, so I might skip a couple places to try to move us through. But I'm Sara Kennedy. I'm with RTI, and this is the evidence report for hyperbaric oxygen therapy for sudden sensorineural hearing loss. And this slide just shows the project team. And here are some abbreviations that you'll see throughout the presentation for reference. So here's a quick overview of the presentation. First, I'll give a little refresher on the policy context, the background, and the methods that were used in this HTA and then we'll focus most of our time on the findings and conclusions.

So as previously mentioned, there was an evidence report on hyperbaric oxygen therapy that was completed in 2013. And this review included several other indications in addition to sensorineural hearing loss. And as a reminder, this project, as we already know, is limited to HBOT just for sensorineural hearing loss. So the previous review was a review of published systematic reviews and not of primary studies. So we did an entirely new search for the current report and included primary research studies. The 2013 report found low quality evidence from eight RCTs with mixed results in the acute phase and that was defined as treatment beginning within two weeks of symptom onset and the report's conclusions were inconclusive regarding whether there was a benefit for HBOT in the acute phase. For the chronic phase, there was moderate quality evidence from two RCTs that suggested no benefit for hyperbaric oxygen therapy. And the coverage decision in 2013 was to not cover hyperbaric oxygen therapy for the acute or chronic phase of sudden sensorineural hearing loss. So this topic was selected as previously mentioned, for medium concerns for safety and high concerns for efficacy and cost and then the Health Care Authority was also aware of new evidence that could change the previous determination.

So now we'll go over some very general information about this condition. Hearing loss broadly can be categorized as conductive or sensorineural, with conductive hearing loss happening when sounds can't get through the outer or middle ear and common causes of conductive hearing loss are fluid, a foreign

body, impacted earwax, or a ruptured eardrum. Sensorineural hearing loss is related to problems in the inner ear, it may involve damage to hair cells within the inner ear, abnormal function of the cochlea, auditory nerve, or higher aspects of central auditory perception or processing. Common causes of sensorineural hearing loss generally are age, noise exposure, blast trauma, and drug side effects, it can also be idiopathic, meaning it has no identifiable cause after proper investigation and it could occur gradually over time or have a sudden onset. So sudden sensorineural hearing loss is a subset of sensorineural hearing loss where significant noticeable hearing loss occurs over a very short period of time. The American Academy of Otolaryngology defines sudden sensorineural hearing loss as hearing loss that occurs within 72 hours and involves a decrease in hearing of greater than 30 decibels affecting at least three consecutive frequencies. So the incidence of sudden sensorineural hearing loss is reported to be 5 to 27 cases per 100,000 people annually, so about 66,000 new cases a year in the US, so not very common as previously mentioned. But this may be an underestimate because people who experience mild hearing loss or who have a quick resolution of symptoms may not seek medical care. More than 90% of cases are idiopathic, meaning we're not really sure what caused them. Dizziness or vertigo co-occur in 30 to 60% of cases and tinnitus is also very common and that can be a really bothersome symptom for some people. Many people with sudden sensorineural hearing loss experience spontaneous recovery and estimates of spontaneous recovery range from 32 to 65%. And as previously mentioned, one of the suspected or theorized etiologies of idiopathic sudden sensorineural hearing loss is, maybe it's related to some hypoxic event that injures the inner ear. We saw that theory kind of referenced in a lot of the background sections of the papers that were included, but we didn't independently like specifically investigate that piece.

So acute acoustic trauma or acute noise induced sensorineural hearing loss is also a form of sudden sensorineural hearing loss, but it's caused by an intense impulse noise. So in this scenario, the inner ear is damaged by a short, intense acoustic impulse and that's also thought to maybe have some involvement with hypoxia and this injury in the inner ear. Some symptoms for acute acoustic trauma tend to include higher frequency hearing loss and tinnitus, but unlike idiopathic sudden sensorineural hearing loss, it almost never includes vertigo. And this is, again, most commonly seen in military or law enforcement personnel, people who are exposed to training with firearms. And I want to note that we'll be reporting the results separately for idiopathic sudden sensorineural hearing loss and then for acute acoustic trauma.

So pure tone average or PTA refers to the measurement of someone's hearing sensitivity. PTA is calculated by averaging thresholds at various frequencies and most often, these frequencies focus on those that represent like normal conversation and that ranges from about 500 hertz to 4,000 hertz. And these results are given to patients on an audiogram that plots hearing levels for each ear with decibels on the y-axis and frequencies on the x-axis. So to put this into context, lower scores are better and higher scores indicate greater hearing loss.

Someone with a PTA, for example 30, may have trouble understanding whispering, certain words with P, H, or G sounds, and birds chirping. Someone with a PTA of 80 will have difficulty hearing even loud sounds like a dog barking or a baby crying and normal conversation without hearing assistance will be very challenging. So this table shows a general grouping of hearing loss severity and there are some differences in how studies use these terms, but they generally fall into categories comparable to this.

So hyperbaric oxygen therapy has been around for a very, very long time. It became used more widely in modern times beginning in the 60s and it has been used to treat decompression sickness in divers, carbon monoxide poisoning, crush injuries, and diabetic wounds. As a very general overview, hyperbaric oxygen therapy involves putting a patient in a chamber with raised air pressure so they can breathe 100% oxygen. The increased air pressure and oxygen level helps the lungs collect more oxygen, which results in the tissue in the body getting more oxygen, which can help heal tissue quicker. Too much oxygen can cause damage to the body, though the risks of hyperbaric oxygen therapy when administered in properly regulated medical facilities are generally considered to be low. And we know this more from broader literature of other indications beyond sensorineural hearing loss. And I'll talk more about this when we get to the findings, but I want to point out now that all of the studies that were included in this HTA were done in hospitals with otolaryngology departments and they use medical grade HBOT chambers. So all the evidence you're going to see in this report is about medical grade HBOT done in medical settings and it is not generalizable to non-medical chambers that deliver oxygen at lower pressures and might be marketed for wellness purposes. So why hyperbaric oxygen therapy for sudden sensorineural hearing loss? The theory that we see in the literature is that vascular compromise and the associated cochlear ischemia is a potential etiology of both idiopathic and sensorineural hearing loss and acute acoustic trauma. The cochlea and the structures within it require a high oxygen supply, but the direct vascular supply is minimal. So the increased partial pressure of oxygen therapy from HBOT allows for more delivery oxygen to the tissue, in this case the cochlea, which is sensitive to ischemia. So the FDA regulates both the oxygen used in the hyperbaric oxygen therapy and the chambers and as previously mentioned in July of 2021, the FDA cleared hyperbaric chambers for hearing loss that occurs suddenly without any known cause.

So this slide gives a summary of clinical practice guidelines on the topic. The American Academy of Otolaryngology stops short of recommending hyperbaric oxygen therapy but they stated that it can be offered along with steroid therapies within two weeks of symptom onset or if other treatments have failed, it can be offered within one month of symptom onset as a salvage therapy. They noted that although hyperbaric oxygen therapy may not be readily available in all regions, their panel felt that the level of evidence for hearing improvement, albeit modest and imprecise, was sufficient to include hyperbaric oxygen therapy as an option for patients. And I'll note that hyperbaric oxygen therapy is almost always recommended in addition to medical therapy, specifically steroids. And you can see that the other clinical practice guidelines reached similar conclusions. I also want to note that these

guidelines are all specific to idiopathic sudden sensorineural hearing loss and we did not identify any for acute acoustic trauma. So we also conducted a review of payer policy documents. As previously mentioned, Medicare and TRICARE have coverage decisions for hyperbaric oxygen therapy, but they do not list hearing loss of any kind among the indications that are covered or not covered, so they're just silent on hyperbaric oxygen therapy for hearing loss.

However, Aetna, Cigna, Humana, Kaiser Permanente, Premera Blue Cross, Regence Blue Shield, and United all consider hyperbaric oxygen therapy medically necessary for idiopathic sudden sensorineural hearing loss and

they cover it with conditions. There is variations in the details of these policies, but in general, the conditions are either related to the degree of hearing loss. Most have a threshold of a decrease in hearing of greater than or equal to 30 decibels and then the other criteria is related to time since symptom onset and most policies require that treatment begin within two to four weeks of symptom onset or in the case of salvage therapy within one to three months of symptom onset. And again, all of these payer policies cover idiopathic sudden sensorineural hearing loss. Aetna specifically excludes noise-induced sensorineural hearing loss, but no other payer policy made a specific statement about noise-induced hearing loss.

So now I'll give a quick overview of the methods that were used in this HTA.

This slide shows the analytic framework and the key questions. Eq1 is on efficacy EQ1A is a sub-question about the optimal frequency, dose, or duration of treatment and EQ2 is about subpopulations. The SQ is about safety or harms and the CQ is about cost effectiveness. So this slide shows a summary of the inclusion criteria or PICOs. The included population was children or adults with acute or chronic idiopathic or noise-induced sudden sensorineural hearing loss. Eligible interventions for hyperbaric oxygen treatments with or without steroids or medical management. Eligible comparators included other treatments or sham hyperbaric oxygen therapy. Outcomes included any hearing-related or patient-centered outcomes and any outcomes about harms or safety and I'll go into more detail about these on the next slide. For idiopathic sudden sensorineural hearing loss, we only included RCTs. And for acute acoustic trauma, we included RCTs and non-randomized studies of interventions. And just as a note, non-randomized studies of interventions or NRSIs is the term we've moved toward for describing prospective or retrospective observational studies. And then for cost, we would have included cost effective outcomes in the US-based settings, but as previously mentioned, we did not find any cost or cost effectiveness data reported from any country. So we search databases back to inception and there were no limits on intervention timing or duration. This slide shows outcomes of interest in more detail. We abstracted measures of hearing recovery, and in this case, we're referring to categorical measures of complete partial or no hearing recovery. And then for the purposes of this report, hearing improvement refers to continuous measures like mean or median change in PTA. We also looked for other patient-

centered outcomes like depression, functional status, quality of life, and the ability to return to work. We included reports of any adverse events or serious adverse events and subpopulations of interest included treatment differences by age, sex, race or ethnicity, disability, comorbidities, type and severity of hearing loss, or treatment settings. And again, we would have included cost effectiveness studies with US-based costs, but we found none.

This slide gives an overview of the general methods. We searched PubMed, Cochrane Library, and clinicaltrials.gov in July. We assessed the risk of bias in RCTs with RoB 2.0 and NRSIs with ROBINS-I. We used R Studio to calculate absolute mean differences and 95% confidence intervals between groups.

And then if three or more studies reported a similar enough outcome, we use data to perform meta-analysis. And finally, we graded certainty of evidence based on the GRADE approach. We used the GRADE framework to assess the certainty of evidence for each set of studies with the same comparison and outcome. The outcomes that we ended up grading based on what was reported in the included studies were a hearing recovery, mean or median hearing improvement, residual hearing loss after treatment, tinnitus, word discrimination scores, and then reports of any adverse events. A high GRADE indicates we are confident in the result and the future studies are not likely to change our assessment. In contrast, a low or very low GRADE means we are less confident and future studies could change the effect estimate. So here is the study flows diagram. Excuse me. We screened a total of 652 unique citations. And ultimately included 17 studies. 10 of these are on RCTs on idiopathic sudden sensorineural hearing loss and seven were on acute acoustic trauma, including one RCT and six NRSIs. And as a reminder, we're reporting the findings separately for these two indications and to be clear, all of the studies were conducted in participants who either had idiopathic sudden sensorineural hearing loss or had acute acoustic trauma, there were no combined populations.

So now we'll move into the findings for idiopathic sudden sensorineural hearing loss. I'll go into more detail on study and population characteristics by comparison. But just as a general overview, studies were conducted in Europe, Asia, and Turkey. We identified no US-based studies. Studies mostly enrolled adults. Two did include a small number of children and the age range across the two studies that enrolled children was 13 to 75 years. Most of the studies only enrolled patients with unilateral hearing loss. And as a reminder, all included medical grade HBOT interventions. This slide summarizes the study's inclusion criteria related to degree of hearing loss and then the duration of hearing loss or the time from symptom onset to treatment. And we paid really close attention to these criteria because they're thought to be important to treatment outcomes and also because these are the factors that were most often included as conditions in payer policies. The figure on the left shows the degree of hearing loss that was required in order to be included in each study. All of the studies that reported a hearing loss inclusion criteria required at least mild hearing loss. The study of salvage therapy enrolled participants who had an improvement of less than 10 decibels after initial steroid treatment and I'll note that the

three studies that did not have a hearing loss inclusion criteria, among those two enrolled participants with hearing loss at baseline ranging from 56 to 92 decibels, so that reflects moderate to severe hearing loss. Then the figure on the right shows the number of studies by duration of hearing loss allowable in those studies. You can see most studies enrolled participants within 15 days of symptom onset. And the two RCTs that didn't have an inclusion criteria around this, the mean time to treatment was less than four days. This slide gives a breakdown of the number of studies we have for each key question. We have the most evidence with seven RCTs for HBOT with steroids versus steroids alone. Then we have a single study comparing HBOT only versus steroid only, and notably, this is a three-armed study that was also included in the HBOT with steroids versus steroids alone group. And then we have one RCT on salvage therapy, meaning it only enrolled participants who failed initial treatment. And then there were two studies for EQ1A that compared alternative HBOT therapies.

This slide gives an overview of study characteristics. These seven RCTs comparing HBOT with steroids were published between 2004 and 2022. The sample sizes range from 50 to 111 participants and follow-up time ranged from immediately after treatment to 180 days. We assessed three as low risk of bias, three as some concerns, and one is high risk of bias and that was due to the possibility of inadequate randomization, a lack of reporting of baseline differences, and their choice of primary outcome. The HBOT treatment began within 14 days of symptom onset in six of the seven studies. The seventh study didn't report time to treatment or the mean symptom duration, but they only enrolled those with symptom onset within the last 30 days. Reporting was somewhat limited for the mean time of symptom duration before treatment with four RCTs not reporting this, but for the studies that reported this, participants were generally getting treatment within three to four days, so in general, this evidence base really consists of participants who receive treatment quickly.

This slide summarizes the number of HBOT sessions, the length of those sessions, and the duration of treatment and the pressure. There was some variation across studies, but generally studies most often included 10, 90-minute sessions once a day for 10 days at 2.5 ATA. Steroid regimens varied widely across studies. There was a mix of oral and IV and intertympanic steroids, and intertympanic steroids are those that are ejected into the ear. And then three studies added hemorheological agents and plasma expanders, which would have been aimed at supporting blood volume and increasing blood flow to the inner ear. And this slide shows the definition of complete recovery, partial recovery, and no recovery as defined in each of the five studies within this comparison that reported categorical hearing loss. And as you can see, there is variation, but also some overlap in the way the study is defined complete, partial, and no recovery. Most were based on improvement in PTA, some incorporated word discrimination scores, and some tied hearing to the unaffected ear, but especially for no recovery, we thought there was enough overlap to group these for analysis. So now we move into the findings for HBOT with steroids versus steroids. This slide shows the key findings for complete or partial recovery. All of the studies in this meta-analysis only included participants who began treatment within 14 days. So

participants who were treated with HBOT and steroids were 39% more likely to achieve complete or partial recovery compared with those treated with steroids. This translates to an absolute risk difference of 180 more people per 1,000 ranging from 14 more people to 396 more people achieving complete or partial hearing recovery with HBOT compared with steroids alone. And I'll note there was a moderate amount of heterogeneity based on that I squared of 44.9% and we think this heterogeneity is likely related to differences in recovery definitions, differences in hearing loss at baseline and differences in treatment regimens. So this meta-analysis includes the same five studies as the previous one, but this shows results for no recovery. Participants treated with HBOT plus steroids within 14 days of symptom onset were 41% less likely to experience no recovery versus steroids. This translates to an absolute risk difference of 127 fewer per 1,000 experiencing no recovery ranging from 180 fewer people to 53 fewer people. And there is much less heterogeneity in this analysis, likely because the definitions used across studies were similar. In addition to the categorical recovery, four of the seven RCTs for this comparison reported mean or median hearing improvement and the findings were mixed. Two RCTs found no significant difference between groups and two RCTs did find a significant difference favoring HBOT. Among the two RCTs that found no difference, there was a mean difference between groups of 8.8 decibels favoring HBOT and 1 RCT, But the difference was not significant. And then in the second RCT, they reported a median improvement of 17.5 decibels in the HBOT group and 22.5 in the steroid group, and that difference was not significant. Among the two RCTs that did find a significant difference favoring HBOT with steroids, one reported a mean difference between groups of 15.9 decibels favoring HBOT with steroids, and the other didn't report underlying estimates, but they reported that the difference was statistically significant. So this slide shows the findings from one RCT that reported word discrimination scores. The score is the proportion of words someone repeats correctly after the word is played through headphones at a volume they've said is comfortable. The words are common and phonetically balanced and include words like boat, pool, or dime. This RCT found improvement in word discrimination scores was statistically significantly greater in the HBOT plus steroid group compared with the steroid group. However, we're not certain if this difference represents a clinically meaningful difference. Now we'll go over the findings reported for subpopulations. So first and foremost, I want to stress a major caveat that was previously mentioned. These were all very small post hoc analyses, mostly from single RCTs that were not powered for these subgroup analyses. Some of the subgroups were as small as 10 people. So we should be really cautious about how much weight we give any of these findings. But briefly, one RCT suggested outcomes were better for those who started treatment sooner, one found outcomes were better for those with greater hearing loss at baseline, while another found no difference by baseline hearing loss, and one RCT found no difference by age and then one found better outcomes for women compared to men. Now we'll move into the safety or harms related findings. So four of the seven RCTs reported adverse events. Adverse events were rare and no studies reported any major complications and there was no significant difference between groups. There were four adverse events in the HBOT plus steroid group. They were all reports of mild ear pain and they all resolved and there were no adverse events in the steroid groups. So we applied GRADE to the outcome shown here and we found moderate certainty of evidence that HBOT plus dairy treatment within 14 days of symptom onset increased likelihood of complete or partial hearing recovery and reduced the risk of no

hearing recovery compared with steroid treatment alone for idiopathic sudden sensorineural hearing loss. For mean or median hearing improvement, there were mixed findings from 4RCTs, and we rated this as a very low certainty of evidence favoring HPOT plus steroids, because the direction of effect across studies tended toward favoring HBOT plus steroids. There was moderate certainty of evidence that HBOT with steroids improved a participant's ability to understand speech based on word discrimination scores and there is low certainty of evidence for no difference in adverse events between groups. And as a reminder, this is the comparison where the bulk of the evidence is.

So now we'll move into the HBOT only plus steroid comparison. We have one RCT that was published in 2022 with 115 participants. That reported on HBOT-only versus steroids only and as a reminder, this is a three-arm study, so it was included in the previous set of results. Briefly, this study enrolled participants with symptom onset in the last 30 days. It did not report the actual mean time to treatment among enrolled participants. Participants in the HBOT arm received a 90-minute sessions once a day for 10 days and participants in the steroid group received oral prednisone. This study did not report actual baseline or follow-up values, and most data were only reported in figures. So I've included a figure from the paper here to give you a sense of the results, we did reach out to the study authors to see if we could get the underlying data, but they did not respond. The authors reported significant improvement in PTA within both groups, and the improvement was significantly greater in the HBOT only group compared to the steroid group. This study reported subgroups by treatment and by time to treatment and sex and treatment outcomes were generally better for those who started treatment sooner and there were significantly greater improvements for women compared to men. Then the only safety findings here was a narrative statement in the paper saying they observed no short or long-term treatment complications. So based on this one RCT, we graded the certainty of evidence as low favoring HBOT. And as a reminder, based on clinical practice guidelines, HBOT would generally always be offered in conjunction with steroids.

Now we'll go over the study of salvage therapy. So this RCT was published in 2013. It included 50 participants and follow-up was after 20 days of treatment. It was conducted in Serbia and we rated the risk of bias as some concerns and the funding was not reported. This study enrolled participants who failed initial therapy and failure was defined as hearing improvement of less than 10 decibels after six days of treatment with IV steroids. All participants started treatment within four weeks of symptom onset and the mean symptom duration was not reported. Participants were randomized to either 20 60-minute sessions of HBOT once a day or to intertympanic steroid injections over a 13-day period. Hearing improvement was only significantly better in the HBOT group compared to the steroid group at one of the five frequencies reported. At 2000 hertz, there was a significant difference favoring HBOT, but the difference was not significant at any other frequency. Hearing improvement was significantly better within both groups from baseline to the end of treatment except for with intratympanic steroids at 2,000 hertz. And it's unclear what the clinical significance of this finding is, especially since it's in the middle of

the, the one that was significant is in the middle of the range of the frequencies that was measured. And there were significant improvements from baselines, from baseline within both groups so the conclusion of this study was that they were both successful salvage therapy options. So hearing improvement was worse with HBOT for patients with more severe hearing loss at baseline compared with steroids and then there was no difference in hearing improvement between groups for those with less severe hearing loss. There were no significant differences between groups in the number of adverse events. Both groups had some participants report mild ear pain and all of the adverse events resolved quickly with treatment. So here is the certainty of evidence for the two outcomes we graded for salvage therapy. We had low certainty of evidence for no effect for hearing improvement and very low certainty of evidence of no effect for safety.

Now we'll go over the findings for the final comparison for idiopathic sudden sensorineural hearing loss and that's related to EQ1A, which compares alternate HBOT regimens. We found two RCTs that compared optimal frequency dose or duration of HBOT. They were published in 2015 and 2023. One included 55 participants and the other 105. Follow-up time was immediately after treatment and three months after treatment. One was conducted in Italy and the other in South Korea and both were rated as some risk of bias. One did not report any funding information and the other reported no external funding was needed. For this section, I'll go over the intervention characteristics and findings separately because the studies compare different types of HBOT regimens. This study enrolled 55 participants with symptom onset in the last 15 days and mean baseline hearing loss was consistent with severe hearing loss. Both groups received HBOT at 2.4 ATA with intratympanic steroids over the first three days. And this RCT compared two 90-minute HBOT sessions per day over a five-day period with one 90 minute HBOT session per day over 10 days. There were no significant differences in hearing outcomes between groups, and both groups improved by a mean of about 29 decibels. There were also no differences by degree of hearing loss at baseline and the authors noted that short order treatment durations with more concentrated HBOT sessions which may be more feasible for patients may have comparable effectiveness as longer treatment durations. The second RCT in this group enrolled 105 participants on average, within three and a half to five and a half days after symptom onset with profound hearing loss at baseline. This RCT compared three groups, one hour sessions at 2.5 ATA, two hour sessions at 2.5 ATA, and one hour sessions at 1.5 ATA. There was similar mean hearing improvements from baseline to the end of treatment in groups one and two, which were those done at 2.5 ATA, and that was of about 53 decibels and then group three, which was done at 1.5 ATA, only had improvement of 36.5 decibels. So group one and group two each had significantly better hearing improvement compared with group three. There were no differences between group one and group two. So this suggests there was no benefit two hour versus one hour HBOT sessions and that 2.5 ATA had better hearing outcomes than 1.5 ATA. And as previously mentioned, 1.5 ATA is a lower pressure than would normally be used and all of the RCTs that were included for idiopathic sudden sensorineural hearing loss, other than this one, they all use pressure between 2.0 and 2.5 ATA. So findings were similar for word discrimination scores within group one and group two improving from about 10% correct or less at baseline to 73 and 76% correct

respect respectively after treatment. Group three improved only to 54% so again, group one and group two were each significantly better than group three. And this slide shows the safety findings. There were no significant differences between groups. All of the adverse events were minor ear pain and they improved after treatment and we did not grade the certainty of evidence for this comparison.

So now we'll move into the studies of acute acoustic trauma. Excuse me. Fighting a runny nose over here. So we identified seven studies of acute acoustic trauma, including one RCT and six NRSIs. Five of these studies recruited from military hospitals or medical centers, and the remaining two were in hospitals. And again, we have no US-based studies with five of these being conducted in Europe, one in Japan, and one in Turkey. And first, I want to explain that we had really meaningful risk of bias concerns for this entire body of literature, specifically, we rated that one RCT, which was published in 1985 as high risk of bias. Due to lack of information about baseline differences and allocation concealment, we also had concerns regarding outcome selection and a lack of blinding for outcome assessors. Three NRSIs were rated as serious risk of bias, largely due to poor or inadequate attempts to control for confounding and three NRSIs were rated as critical risk of bias due to no attempt to control for confounding. I also want to note that because these studies didn't adequately address confounding and because group allocation was often based on factors that might predict outcomes, we have little confidence in their results, but we also didn't see anything in the literature that would suggest the mechanism of action for HBOT would be different for acute acoustic trauma versus idiopathic sudden sensorineural hearing loss. And as you'll see throughout this section, the methodological issues led us to have little confidence in the results of each study, but the results did consistently favor HBOT. So this slide lays out the comparisons of the included studies reported and which key questions they addressed. First, we'll go over the results for HBOT with steroids versus steroids. All three of the studies for this comparison are NRSIs published between 1995 and 2020. Sample sizes range from 41 to 78, and follow-up ranged from six and a half days after treatment to one year. They were all conducted in Europe. Two were rated as serious risk of bias and one is critical and the study radius critical risk of bias, treatment group selection was unclear, and the authors made no attempt to control for confounding. In the two studies rated a serious risk of bias, one study allowed participants to self-select treatment groups and those with more severe hearing loss selected HBOT. And then the other study, participants were selected into HBOT groups based on the ability to be evacuated to a military hospital. Two of the studies explicitly reported firearm shots for the cause of injury and this evidence is again based on participants who receive treatment very soon after injury. Baseline hearing loss varied from a loss of 22.6 decibels to 46.6 decibels and in these studies, pre-injury hearing measures were often available because hearing was measured at entry into military service. Hearing loss was most severe at higher frequencies, which is consistent with acute acoustic trauma and steroids varied, they included oral steroids, IV steroids, and combinations of IV and oral steroids. Mean hearing improvement significantly favored HBOT with steroids compared with steroids alone. One study reported residual hearing loss, which was calculated based on PTA at enlistment into military service and this significantly favored HBOT with steroids over steroids alone. And one study reported impact on tinnitus and found no significant no significant difference between groups.

Two of the NRSIs made narrative statements that no side effects or serious side effects occurred. And here is a summary of certainty of evidence for acute acoustic trauma of HBOT with steroids versus steroids. For mean hearing improvement, there was a low certainty of evidence from three NRSIs that favored HBOT with steroids compared with steroids alone. For mean residual hearing loss, there was a low certainty of evidence from one NRSI favoring HBOT with steroids compared with steroids. And then we found very low certainty of evidence for no effect for both tinnitus and adverse events.

I'll go over the study that compared HBOT with a control or usual care other than steroids. So we identified one RCT and one NRSI, and notably the RCT was published in 1985 and rated as high risk of bias for all of the reasons previously mentioned. And the NRSI was rated as serious risk of bias due to poor control for confounding. The cause of acute acoustic trauma was exposure to firearms or explosives during military service. Mean symptoms range from 17 to 72 hours, so again, this is evidence for people who got treatment quickly. And the RCT compared 10 60-minute HBOT sessions plus infusions with plasma expanders with and without an anti-vertigo medication with infusions alone. The NRSI reported the mean number of HBOT sessions participants received was 3.2 sessions for 90 minutes once a day and this was compared with a mean of 6.2 sessions of normobaric oxygen therapy which were 90 minute sessions twice a day. And an NBOT or normobaric oxygen therapy, participants breathe 100% oxygen but there's no additional pressure. The RCT reported a greater proportion of participants who received HBOT with infusions achieved hearing recovery compared with those who received infusion only. The NRSI reported a greater proportion of participants who received HBOT experience recovery at high frequencies compared with NBOT at high frequencies and AAT is most likely to impact hearing at high frequencies. The NRSI reported significantly fewer participants who received HBOT reported tinnitus compared to those who received and bought so this finding favors HBOT. The RCT reported one adverse event of sinus barotrauma in the group receiving HBOT of infusions of plasma expanders and one adverse event of oxygen intoxication in the group receiving HBOT with infusions of plasma expanders plus anti-vertigo medications and both participants recovered. There were no adverse events in the infusion only group and the NRSI did not report on harms. So here is a summary of the certainty of evidence for HBOT versus control or usual care. We had very low certainty of evidence for hearing recovery favoring HBOT and low certainty of evidence for hearing recovery at high frequency, also favoring HBOT. For tinnitus, there was very low certainty of evidence favoring HBOT based on one NRSI and for safety, there was very low certainty of evidence for no effect based on one RCT.

Now we'll go over the results for early versus late treatment. For this comparison, we have one NRSI published in 2015 with 73 participants. It was conducted in Turkey and we rated it as critical risk of bias due to no attempts to control for confounding. This study enrolled participants who sustained injury resulting from firearms. Patient self-selected treatment, mainly based on their belief about whether or not their hearing would recover spontaneously. Both groups received 10 to 20 90-minute HBOT sessions and oral steroids. And this study compares those who started HBOT early or within 10 days to those who

started late or within 11 to 30 days. There was no statistically significant difference in complete, partial, or no hearing recovery between the early and late HBOT treatment groups. They reported two adverse events with HBOT, and we did not grade these outcomes.

Now we'll go over our final comparison, which compared alternative HBOT treatment protocols. We identified one in RSI that compared two protocols, it was published in 2019, it included 35 participants, was conducted in Japan and we rated it as critical risk of bias due to no attempt to control for confounding.

This study also enrolled participants whose acute acoustic trauma was caused by exposure to firearms. They compared HBOT protocols based on two different US Navy treatment tables. The first protocol, which was called TT5, only included seven participants and involved sessions that were two hours and 15 minutes long done at the equivalent of 0.9 ATA. The second protocol, called TT9, included 28 participants, and it involved sessions that were one hour and 45 minutes long at a higher pressure. There were no significant differences in mean PTA at lower frequencies between the two protocols. There was a significant difference favoring TT9, which involves shorter sessions at a higher pressure for recovery at higher frequencies, and we did not grade this comparison.

Now we're going to revisit the certainty of evidence grades that were previously presented for each section. This slide summarizes the certainty of evidence for idiopathic sudden sensorineural hearing loss for each comparison and then outcome. So the strongest evidence comes from studies comparing HBOT plus steroids with steroids. As a reminder, we have moderate certainty of evidence that indicates that participants who received HBOT with steroids were 39% more likely to achieve complete or partial recovery and 41% less likely to experience no recovery compared to those treated with steroids. Safety data from four RCTs, including 281 participants, found no major complications and rare minor adverse events, primarily mild ear pain with no significant differences in adverse events between HBOT plus steroids versus steroids alone.

Evidence for other comparisons was more limited. There was low certainty of evidence from a single RCT that HBOT alone significantly improved hearing compared with steroids alone. And this evidence may be less relevant because HBOT is generally considered in conjunction with steroids. The study of salvage therapy found no difference between HBOT compared with intratympanic steroids and concluded that both are reasonable salvage therapy options.

And now here is a summary of the certainty of evidence ratings that were previously presented for acute acoustic trauma. For acute acoustic trauma, there was low to very low certainty of evidence across all reported outcomes which really limits our ability to draw meaningful conclusions. The largest body of evidence included three studies, all of which favored HBOT plus steroids versus steroids only for hearing

improvement outcomes. There were two studies comparing HBOT to either usual care or NBOT and findings again favored HBOT, but our certainty was low or very low. And our findings were consistent with another systematic review that was published in 2022 on idiopathic sudden sensorineural hearing loss. This review included a smaller number of RCTs, but also found hearing improvement significantly favored HBOT. And we only identified one RCT of salvage therapy And it found no difference between HBOT and intratympanic steroids but both groups significantly improved from baseline to post-treatment, so the authors concluded both could be reasonable options. And I want to note that we're also aware of a systematic review specific to salvage therapy that included non-randomized studies and that compared five treatment regimens, and they found the largest improvements for HBOT when it was combined with intratympanic steroids. Also, I want to highlight that the clinical practice guideline for the American Academy of Otolaryngology recommends offering HBOT combined with intratympanic steroid therapy within one month. And the rationale for this was really thought that though there is stronger evidence for early treatment, there are a lot of logistical reasons that might delay getting patients into an HBOT chamber. And then, so salvage therapy, after initial therapy failed and delayed treatment are areas where we really could use more research. There's a lack of evidence here.

And then there are several limitations of the current HTA, some of which were previously mentioned, but briefly, these were all generally small sample sizes. None of the studies were conducted in the US. The steroid and HBOT regimens varied. The studies defined hearing recovery in different ways and this literature didn't really give us a very clear sense of what degree of hearing recovery is clinically meaningful for patients. Different studies averaged different frequencies to calculate PTAs differently and that could impact results, though they were all generally using frequencies that reflect conversation. There were meaningful methodological concerns, especially for the acute acoustic trauma studies. Studies generally included short follow-up periods and then finally, no studies reported cost effectiveness data. One study made a comment in the discussion that steroids were less expensive than HBOT, but they didn't provide any data or a citation for this, though it's almost certainly true. And then key limitations of this report are that it was limited to peer review studies published in English. We also limited to studies that were conducted in countries categorized as high on the UN or very high on the UN's Human Development Index. And then for idiopathic sudden sensorineural hearing loss, we limited study designs to RCTs. We did do a search of clinicaltrials.gov, but we did not find any especially relevant ongoing trials. There is a prospective cohort recruiting in South Korea, and then another study of acute acoustic trauma in a military population, but that study had a target completion date of 2020 in clinicaltrials.gov, and we found no results, so we don't expect it to ever be published.

And then the conclusion for idiopathic sudden sensorineural hearing loss is that our findings suggest HBOT may provide meaningful additional benefit when combined with standard steroid therapy for idiopathic sudden sensorineural hearing loss particularly for those who can begin treatment promptly. And then for acute acoustic trauma, our ability to draw conclusions is really limited by low certainty of

evidence across outcomes. Though the direction of effect tended to favor HBOT, and we have no reason to suspect the mechanism of treatment for HBOT is different for acute acoustic trauma compared with idiopathic sudden sensorineural hearing loss, we don't know for sure how relevant the idiopathic sudden sensorineural hearing loss literature is for acute acoustic trauma. Are there any questions?

Janna Friedly

Thank you so much. Just a procedural thing. I think given that we're running a little bit ahead of schedule. I think we should do our question and answer. Related to the report now and then we'll take a break after we do that. We have a question from Dr. Rubinstein.

Jay Rubinstein

Yeah, a couple of comments. My previous comments about pathophysiology applied only to sudden sensorineural hearing loss. They did not apply to acute acoustic trauma where a metabolic injury, there is evidence to support, in animal studies of acute acoustic trauma. So the irony of these presentations is that it makes a lot more sense to treat acute acoustic trauma with hyperbaric oxygen than it does to treat sudden sensorineural hearing loss. A couple of comments about the presentation. You know, the you know the results are compelling when you look at any recovery or no recovery but the results are far less compelling when you look at the degree of recovery. So, for example, that it was mentioned that that speech discrimination improvement is of questionable clinical relevance, it's more than that. That 10% change in the, I think it was in about 56% versus 66 or something along those lines. Even in an individual receiving a speech discrimination test, 56 and 66 are statistically indistinguishable from one another. So even though in the population there was a statistically significant difference of that amount, that amount is not statistically significant within an individual. In other words, it does not represent a statistically separable data point and it's also not a clinically meaningful difference in overall ability to hear. And I think it was also mentioned that one of the reviews showed a 10 dB improvement in hyperbaric versus steroids or hyperbaric plus steroids versus steroids alone and that 10 dB improvement across the range of hearing losses that these patients have is also of, you know, pretty marginal clinical benefit. But the other thing that was also compelling to me was the comment of the Regence person that came on that the overall cost of this is really low. Those are my thoughts.

Janna Friedly

Great. Thank you. Any questions for Sarah about the report from the committee? Okay, hearing no specific questions, thank you for the report and I think we will move to take a break. We have a 10 minute break scheduled. It's nine, almost 9:50 why don't we reconvene at 10 o'clock And then we can have discussion and talk about a decision. Okay, so we'll reconvene at 10 o'clock.

Josh Morse

Thanks, Janna. I'll put the agenda up while we're on break.

Janna Friedly

Looks like we're waiting for just a, a couple of people to come back. You can put your video on when you get here so we know you're here. So we're waiting for one, one last person that looks like Chris is not on. But the next, the next part of the agenda is to really hear from. There we go. Okay, now that we have everyone back, this next part of the agenda is to just hear from the committee, have some discussion about the evidence and where we're standing and then um, and then take a straw poll vote on a decision. Before we take a straw poll vote, I would like to hear from the committee about any thoughts or questions for the clinical expert or?

Tony Yen

Janna, maybe I can start?

Janna Friedly

Sure.

Tony Yen

I was very skeptical of this hyperbaric oxygen treatment for treatment of, treatment for treatment of the sensorineural hearing loss, because I couldn't understand the biology or the pathophysiology that underpins the rationale for this treatment. And thinking about how hyperbaric option works and increasing like the saturation of uh plasma, you know, the amount of option over there. It's really just a very small amount, if we're to look at this in total. We can just bore each other with like the oxygen saturation curves and all that sort of stuff but yeah, I couldn't understand that at all. For me, the literature does speak up I think it's on took some notes out her, slide 97, the evidence report I think for me summarizes it uh at least what the literature informs me overall bearing HBOT plus steroids against steroids alone there seems to be some compelling evidence. I'm at this kind of interesting position of not understanding why this actually even really works. I think there's a lot of hypotheses that are out there, but the literature does say that it likely does work, acknowledging that there are Studies are relatively small. That's where I'm at right now.

Janna Friedly

I'm not sure which slide you're referring to. You said 93?

Tony Yen

Sorry, page 97 of the evidence report. Yeah.

Janna Friedly

Oh, 97 of the evidence report.

Tony Yen

Yeah, that's the one that really kind of helps guide me In terms of like the understanding of understanding HBOT for sensorineural hearing loss.

Janna Friedly

Yeah. Yeah, I have to say I am in the same boat when I, when I first started reading about the topic before the meeting, I couldn't understand. And I understand hyperbaric and have looked at this for other indications in my own clinical practice and in other So I couldn't quite understand how it would work for this and wasn't aware prior to this that it was being used for this and then saw the evidence and it looks like there's, although there's some mixed results, that there's at least some indication that it may be more helpful. But I'm really trying to reconcile what our clinical expert is telling us that it doesn't make sense from a biologic pathophysiology standpoint. And some of the results are probably not clinically meaningful and so I'm just trying to understand why, if there's any speculation as to why these trials are showing positive results in that context. I know Dr. Rubinstein, you suggested that you didn't really have a good explanation. Do you have any, any thoughts as to why there's that discrepancy?

Jay Rubinstein

So I'll ask the RTI folks that question. How is it that there can be such a marginal change in hearing level and yet the overall results show statistically significant evidence of benefit?

Sara Kennedy

Yeah, I think that's sort of the difference between something being statistically significant and clinically significant might be two different things. And that was something we were unclear on, on this report. But we did see we did studies that reported hearing improvement that was greater with HBOT plus steroids versus steroids. And I think I'll just offer, you know, we look at the evidence and kind of apply or experts in the methods to apply to these studies, but the thinking in the papers of the people who are publishing on this, they do seem to have a different take on things that things they are that it could be some sort of hypoxic event in the ear. I think there's a lot of like theorizing and no one's certain, but there was more diversity of thinking around that in the papers that we reviewed.

Jay Rubinstein

I'll be rather frank about the reason for that is that people are ignorant of temporal bone histopathology across the field of otolaryngology and otology specifically, because a lot of the histopathologic studies of this kind of stuff are old. And so there's a fair amount of ignorance of just what the histopathology of an ischemic injury to the inner ear looks like and the fact that it looks nothing like the injury that is associated with sudden sensorineural hearing loss. But again, having said that, what would I tell a patient now Your report is fantastic. What I told patients before is that you could do this my academy includes this as a potential treatment, but I personally wouldn't do it because I don't think it's beneficial. My, based on your report, I would change the wording of that to well, the evidence indicates a higher likelihood of some recovery and less likelihood of no recovery, but the benefit appears to be fairly marginal and people could choose whether to proceed or not based on that, that's how I would counsel a patient now. Based on what I've seen, I myself personally would not still not do hyperbaric oxygen, because I don't see that the hearing benefits would be frankly worth the amount of time involved.

Evan Oakes

Janna?

Janna Friedly

Yeah.

Evan Oakes

Yeah. I don't know if it might be a little bit of a question for you comment if it because it's mostly me thinking but I, um, It brings up the thing that always has been the case for me on this committee, which is really trying to look at the evidence and what it's showing us and the role of this committee, which is around coverage for these things and when you said that, Dr. Rubinstein made me think of that, right? It's like our committee is not telling people to do that procedure and yet we are looking at the evidence

and trying to make it available for people to do that when it's when it when the evidence supports that. that's a challenge, obviously, as usual. But that's a thought I had as I listened to that comment. I think that that's a good thing and I would hope that our physicians out there are making good decisions for their individual patients and yet this committee is about making recommendations on coverage under the PEBB and the L&I and so forth. But thank you. That's a thought I had. I thought I'd share.

Jay Rubinstein

I said what I would do for a patient of mine. Were I a member of the committee based on the compelling nature of the evidence, I would vote to support it despite my own personal opinions about it.

Janna Friedly

John?

John Bramhall

Janna, I have to say. You know, my professional medical career is anesthesiology, as you know, and we don't know how it works.

I mean, I know that's a bit of a broad brush, but we don't know how it works. So I have a sort of predisposition to accepting data that it just doesn't quite satisfy say that, that itch that you have to know, well, how is it working you know. I had the same reaction as Tony to page 97. That synopsis slide there, it's flashing green. It's not the usual green that we get, sometimes our green is good in a strength of evidence, but it's flashing green everywhere. There's nothing, don't do this. The certainty of evidence is reasonable for a few of the studies. And I thought that the report that we got today was very useful indeed.

Yeah, I actually was quite taken by the outside comments from the audience. Ms. Quinn was the patient who, who presented us with this very human situation. A sudden change in physiology, what to do fear, frighten goes to clinical team and their hands are tied. They really push and shove and try to get something going. The presentation from Regence medical member also was you know it, it, um, it was a presentation a short presentation, a comment really, that look this isn't going to cost very much, we really don't like tying physicians hands unless we have to and here it would be, they thought, I don't know if it's cost effective, but not very costly. So my sort of position at the moment is that the evidence seems to suggest that however it works, whatever the mechanism, this is having some benefit to some patients. It's not a particularly common procedure. It's not something that costs the HCA an awful lot of money. The insurance carrier contracted with HCA, seems to sort of be neutral, maybe neutral, maybe

slightly in favor of liberalizing the payments for this. And so generally it's generally, it's not a straw poll, but I think it's something that would be we could cover.

Janna Friedly

Other comments from the committee members before we take a poll? Laurie?

Laurie Mischley

I agree with everything John just said. I'll add as coming from the naturopathic community, I also expected this to be a quick no before I dove into the research, just because of all the wellness use of hyperbaric oxygen. So, I think the data is certainly consistent and positive. Just tying in the comments from the start of this meeting until to here, I don't love that we are out of the gate dismissing all observational research. I'll just say it again. It's legitimate research. I believe only RCTs were included. We may interpret it differently, but I don't think it's fair as scientists to say just because it's not an RCT doesn't mean it's worth considering in our evidence report. So I just want to make sure that that gets said. I worry about you know, it's not easy to have a hyperbaric oxygen center popping up all over the place and so I think that the people in Western Washington are at a unique advantage. There's going to be additional obstacles, not only in the whole getting into a clinic, finding a doctor, realizing this is serious and time sensitive, but there are a lot of places in underserved communities where the distance to a facility is going to be a whole other barrier we're not looking at, so I just want to kind of think that through and say any additional barriers we can relieve, let's try and do that because it's not going to be easy for people to access this if it's effective. I think there are thousands of things that we use and do that seem to be effective that we don't understand the mechanism of action. Our charge is not to understand the pathophysiology, I mean, in a pragmatic sense, is this something that could help the people we're trying to help. And so just because we don't understand it, I don't think is a good reason to not approve it. We used limes to cure scurvy for 200 years before ascorbic acid was discovered. I mean, if we wait for us to understand the mechanism before we say okay, we could run into a big problem. So philosophically, I think that's important. And we're talking about clinically relevant improvement and I understand the topic is hearing, but we have to also realize like, you know, 10 decibels, great, but we're all getting old and hearing loss is one of the major contributors to modifiable, modifiable contributors to dementia. And so even though we're only talking about can you discern little words here or 10 decibels there, you add that to age, you add this to this, I'm just wondering if why wouldn't we do what we can to preserve people's senses if it doesn't cost that much and the data seems to be consistent? So there may be consequences beyond 10 decibels of word discernment that we're not considering here.

Janna Friedly

Thanks, Laurie. Chris?

Chris Hearne

Yeah, I just, I agree with the general thrust of what Laurie said and what John said and what others have said. I think it's always very nice to understand the biological mechanism of a treatment or an intervention, but I don't think it's necessary to establish causality, it can be very useful to help establish causality but I think our charge here is to essentially be empiricists and so um, while I agree it would be really nice to understand why, if we have other evidence that suggests that it does in fact work, I don't see that as a reason for holding us up for approving it under some set of conditions.

Janna Friedly

Thanks. And Dr. Rubinstein.

Jay Rubinstein

Just to comment back on Laurie's comments that unilateral hearing doesn't contribute to dementia and certainly 10 decibels of unilateral hearing loss is not going to protect you from getting dementia and again what we're talking about here, sudden sensorineural hearing loss by definition is a unilateral process and, uh, that was actually one of my concerns that some of the studies allowed people with bilateral hearing loss. And that's potentially extremely different animal. And I'm not suggesting at any point that we need to understand the biological mechanism of efficacy to determine that something is efficacious. As a surgeon, I do all sorts of things that I don't understand how they work, but the evidence shows you know clearly that they do. The issue is the issue the question of the evidence, because there's a lot of evidence numbers that go into these outcome measures. There's multiple data points for each frequency of hearing. And when the overall evidence is that the, the improvement in hearing is small, it makes you question the overall result. Is this not some sort of statistical outlier that's occurring because of all the different data points that are going into this. But I don't think we're going to get to the bottom of that and hence my comment was the overall evidence is compelling to support, so despite the fact that I don't buy that it's actually doing what it's purporting to do. I would support it.

Janna Friedly

Any other comments? On the committee.

Janna Friedly

Okay, so I think at this point we should move to a formal straw poll vote before a final vote.

Josh Morse

So we do have our, our process slides which, um, slides which I think Val is going to bring up today and I think Melanie will guide through that process and they will correct me if I'm wrong about who's doing what.

Melanie Golob

Yeah, and we can kind of go quickly through the first part because you've already sort of talked through a lot of this and get to the straw poll, but Val, if you want to go to the next one. So these first ones are just kind of showing what you've done so far and the stage that we're at now, which is this last step, which is the discussion and the draft determination and voting.

Go ahead and go to the next one. And these are kind of important considerations, which you've already kind of touched on. You can go to the next. And again, what, what should be thought of for those three factors for safety, efficacy, and cost, availability of the evidence, confidence, and applicability to the decision. Go ahead and go to the next one. And then overall considerations for the evidence and then at the bottom, giving that greatest weight to valid and reliable evidence. Next. And this is just kind of the overall what goes into the determination, not just what's from the reports but also what the alternatives are and comparisons to alternatives and then other info from the public comment, from the director, advisory groups. Next. And then this is just kind of an what happens next? I know we kind of discuss what happens, but so discussing those outcomes and if the outcomes are sufficient and then voting on the sufficiency of the evidence and then discussing if that's If that's enough and then straw poll vote for coverage, and then coming up with coverage conditions as needed and then voting on draft coverage. If you go to the next. So first question, are those safety outcomes for this topic? These were the safety outcomes presented in the report and the question here is are those sufficient ones to make a determination? Are there others that you would have liked to have seen that weren't presented in the studies? That's the first discussion item.

Janna Friedly

I guess I have just a general question, maybe somebody who has more experience with generally with hyperbaric oxygen treatment can answer this but there are other potential complications from complications from complications from hyperbaric that I didn't really hear as like hypertension, headaches um that I've seen in patients. Are those things that I didn't see those reported at all are those not of concern? Does anybody have other any other?

Sara Kennedy

They were reported in this body of literature, but it's a narrow subset of what hyperbaric oxygen therapy might be applied to.

Tony Yen

What do you think about just adding them in addition to the safety outcomes like hypertension and headache?

Janna Friedly

Sure, we can add it. I just didn't see any real discussion or mention of it at all. So I just wasn't sure if it was the way that it was being used or if that's not a concern with this type with the way, way it's being done.

Tony Yen

And also the protocols that you use, Janna, are they similar to the protocols discussed?

Janna Friedly

I don't know.

Tony Yen

Okay.

Janna Friedly

That's why I was asking. I don't know if the protocols are different. Dr. Rubinstein?

Jay Rubinstein

Yeah, I mean, I see a fair number of patients who get HBO for, for things like osteoradionecrosis and other things related to the treatment of head and neck cancer. And the main complications I see, and again, they're uncommon, our middle ear complications from barotrauma. I know of no headache and hypertension issues. I mean, the middle ear complications that you're listing there right now are included in the three first things, which are sort of three different levels of barotrauma.

Janna Friedly

Great.

Melanie Golob

Janna, do you want to move on to the efficacy outcomes? Okay, great. Thanks, Val. So here are the main efficacy outcomes. And again, are there other ones that you would have liked to have seen to help kind of make the determination or is this all that's needed?

Janna Friedly

I think that's sufficient. Covers the broad category hearing improvement covers.

Melanie Golob

We can go to cost. So in cost, there's cost It's pretty straightforward. I don't know if there's any other uh cost related outcomes people would have liked to see. Okay. And then special populations. I don't know if there are other special populations that are missing or if there were special populations for this.

Janna Friedly

I think we heard that there was not data, to suggest that there was any differences or any good data on subpopulations available.

Melanie Golob

Val, do you want to move on to the voting questions for sufficiency of evidence for these three safety efficacy costs. Looks like starting with safety.

Val Hamann

Yeah, so if you could log in to ttpolls. Let me. And when I see eight connections, I will launch that poll. Oh. Okay, we have eight. And we will go through sensorineural hearing loss first, and then we'll go through the acute acoustic trauma. We will move on to efficacy. We'll move on to cost. And now we will be back to the top for safety for acute acoustic trauma. And onto efficacy. And onto cost. And that would be all of those which we can look at again.

Janna Friedly

Okay. Yeah, so. I think the, the some obviously some mixed some opinions, but I think generally follow what I would expect based on our conversations. To me, there weren't any surprises in the voting.

Melanie Golob

So Janna, from here, you can discuss more on the sufficiency of evidence or the results of those votes, or you can move on to a straw poll.

Janna Friedly

Yeah, I think we can move on to a straw poll.

Melanie Golob

Okay.

Val Hamann

And that is live. So that's six for cover with conditions and two covered unconditionally.

Janna Friedly

Okay.

Val Hamann

We're waiting on one more response. Two for not covered, five for covered with conditions and one for covered unconditionally.

Janna Friedly

Okay, so a little more split in the votes there. I don't know if that's uh do, do we want to, does anybody want to talk specifically about the acute acoustic trauma? First, I have to say I struggled with this one. I went back and forth between not covered and covered with conditions because of the I feel the evidence is lacking compared to the sensorineural loss, but I um, but I was swayed a little bit by the argument that there's more plausibility of why it would work in that population and there was a little bit of evidence, so I went with coverage with conditions, but I was on the fence. Yeah, Jonathan.

Jonathan Staloff

I'm happy to provide context on my votes. I was a covered unconditionally with both treatments. I think, I would say I'm very swayable to covered with conditions. I just had a hard time envisioning what those conditions might be. I think for acute sensorineural hearing loss, if a conceptualization of conditions is that it must be within a certain time period, then I'm certainly swayable to a covered with conditions. For the acute acoustic trauma, I just had a hard time envisioning what conditions might be and so in my mind, it was more of a binary decision of covered or don't cover rather than an indication of supreme confidence versus moderate confidence.

Janna Friedly

Thanks, that's helpful. Anyone in the note, no cover category that wants to share their rationale for?

Tony Yen

So I voted to cover, not cover acute acoustic trauma because I didn't feel that the evidence was strong enough. I'm willing to hear are kind of the rationale for others of you know how you interpret the evidence, that's really the bottom line.

Evan Oakes

I had similar logic to what Tony shared. I voted not covered and thought the confidence in the evidence was low in that case, the studies that we were looking at. So that was my logic.

Janna Friedly

Any other discussion about that, from anyone else? If no more discussion, I think we'll just, we'll move to, to, a, a vote or discuss.

Laurie Mischley

Discuss the conditions first?

Janna Friedly

Yeah, so it looks like it looks like the way, so for sensorineural hearing loss it's clear, I think that we're, we're looking at covers covered with conditions. With the acute acoustic trauma. I think, if people are sticking with their current, you know, unless anyone is swayed to change their decision, then it looks like we are also covered with conditions. Yes, Evan?

Evan Oakes

I felt like I should say just a little bit more. I'm trying to figure out how to be, I don't know if I'll ever get there, but I'm trying to figure out how to be consistent in my review, sort of what Tony was referring to. And I just felt like our grids around the covered for SSNHL, the strength of evidence seemed to be stronger for those randomized controlled trials. The trials were different.

For the grid, for the acute and much lower strength. So I just thought I'd elaborate a little bit more, I don't think I did a good job of that earlier and I'm just trying to be sensitive to that as we get feedback over time. It's something that I want to try to listen to and stuff like that. So that was a little bit more of my logic that I'd share.

Janna Friedly

And Jonathan, you had another?

Jonathan Staloff

Yeah, as someone who's debating switching from unconditional to covered with conditions, if there was anyone who voted for cover with conditions, I would love to hear what their sort of conceptualization of what types of conditions came to mind for each indication. Understanding that we're not creating those conditions right this moment, but just to hear how other are conceptualizing that option.

John Bramhall

First well so personally speaking, my condition in the back of my mind has to do with this time course. We've seen sort of a suggestion from other carriers. I know we're our own deal, but other agencies that have put a time limit on the therapy. The problem, well, not to get into it too deeply, but one problem is, is the one that Laurie alluded to that you're out in in the Palouse and it's going to be 10 daily hyperbaric, hyperbaric exposures that you're required to undertake, getting all that together and getting the referral and having it happen may very well take a longer period of time than clinically ideal. And I think that's why there's a range of time constraints. But that was my condition in my head was probably can't do this a year out and maybe no one would.

Jonathan Staloff

Thank you.

Laurie Mischley

The other condition I was thinking is pressure. I mean, we had a study that said 1.5 ATA didn't work and 2.5 did. So I don't know if we want to include that in the conversation, but it looked like there was a threshold that needed to be reached to get the effectiveness we were looking for.

Sara Kennedy

And I'll just note that one study was sort of an outlier. I think when treatment is done, it's normally at, at least two or 2.5 ATA. Some of the other payer policies do call out specifically a minimum pressure, but if patients are receiving this in a medical setting, I think it's probably a very safe assumption that it will be at higher pressure, but it would not be unreasonable to put that in.

John Bramhall

Sara, there was one comment that you made about, um, a Navy protocol in one of the studies and the Navy protocol seems to have, it goes as low as 0.9 atmospheres. This is putting you on the spot, I know. What is that Navy protocol? What's it designed for? Is it designed for acute changes in in hearing or is it designed for people who've fallen out of a submarine?

Sara Kennedy

Yes, that was an old paper with a small sample size using a protocol that nobody's using. I would spend no energy on that paper.

John Bramhall

Thank you.

Sara Kennedy

Everyone is, all of the RCTs are doing this at 2 or 2.5 ATA, somewhere in that range.

Jay Rubinstein

The Navy tables come from subjecting recruits to decompression sickness a long time ago.

Janna Friedly

Can I ask a question about severity of hearing loss? So in my mind with the conditions the literature clearly seems to suggest 14 days to me. I understand that there's some logistical issues with that, but clearly that's to me what the evidence suggests and also there's some suggestion that you know more, more severe hearing loss makes more uh, is more likely to benefit. Those definitions that were provided in the beginning about moderate to severe or profound hearing loss. Are those clinically, universally used or is that like if you included some, some language around severity or is that going to lead to confusion clinically and variability? And is that something that from a clinical perspective you would not recommend including in there and leaving it up to the discretion position or if, if you were? That's directed to you, Dr. Rubinstein.

Jay Rubinstein

Yeah, so I mean, if one proceeds from the belief that this is an effective intervention. Restricting it to two weeks doesn't make sense to me. And the reason is the natural history of sudden sensorineural hearing loss is that it gets better over about a month. There are some people who will continue to improve after a month. So what I typically tell patients is your hearing at six weeks is almost certainly what you're hearing is going to be long term. So there does appear to be capacity for improvement within that first month. If, for example, I see a brittle diabetic you know who's within a month of onset, I'll still treat them with steroids because to me, the potential benefits outweigh the risks of driving their blood sugar into the stratosphere. If I see a brittle diabetic after a month. I won't treat them. If I see a healthy 25 year old after a month who's got profound deafness in one ear, I will treat them. And so to me, the similar question would be, well, you've got a healthy young person who's three weeks out who's got profound deafness in one ear, you know, there's evidence that this thing works, you know, and the evidence is pretty good out to two weeks, I think I probably want the option to treat that person. So to me, the academy's criteria in terms of timing makes sense, even though I agree the evidence really only comes out to two weeks.

Janna Friedly

And just to be clear, when you say the academy, you're saying that the AAO HNS, the 2019.

Jay Rubinstein

I mean, they.

Janna Friedly

Within to HBOT combined with steroid therapy within two weeks of onset or as salvage therapy within one month of onset? Is that what you're referring to?

Jay Rubinstein

Yeah. And to me, you know, what's salvage therapy and what sort of adding to therapy because early on the patient's not getting better. As an example, if I see someone within the first couple of days of onset, I'll put them on oral steroids and see them back in a week and do a hearing test. And if there's no improvement at that point then I'll do intratympanic steroids as well. Which, you know, there's evidence that intratympanic steroids results in higher concentration of steroids in the inner ear then you can achieve with systemic steroids. So as time goes on, I'm bumping up the degree of intervention.

Janna Friedly

Yeah.

Jay Rubinstein

The word salvage implies something that, you know, that within my treatment protocol wouldn't be used. It's basically just doing the upping the intensity of the intervention because of the failure to improve. That's part of the natural history.

Janna Friedly

Yeah, so it sounds like.

Jay Rubinstein

The natural history is that this is going to get better over four to six weeks Or it's not.

Janna Friedly

Yeah. Okay, Jonathan and then Evan.

Jonathan Staloff

Yeah, I very much appreciate the 14 days being sort of the time marker in the evidence base. I think for when thinking about conditions, I really struggle with that time frame and I would prefer a longer one, just thinking practically, as a family physician in Seattle, where I would say there's probably more access. If someone has a symptom on a Monday. I might say like good luck getting to be on my schedule within two weeks. Being the beneficiary of being on this committee, I think I maybe know more about acute sensorineural hearing loss than others now, but I can't say I would make that diagnosis and so then I would refer to someone like Dr. Rubinstein, at which point I would say, good luck seeing him within a two week timeframe. And then you would have to rely on him suggesting hyperbaric oxygen therapy as a possibility. And so I just feel like just the practicalities of the steps an individual would need to take for hyperbaric therapy to be even on their radar, I just don't think is even remotely feasible in a two week timeframe from symptom onset.

Janna Friedly

That's great points.

Evan Oakes

Yeah, I was going to comment kind of similarly. I appreciate the timeframe conversation. I sort of feel like There should be a timeframe of some sort, given what we looked at for evidence. Perhaps we need to bump it out to some reasonable amount, but it doesn't seem like we'd want to approve this for say six months out and say you can just use, you know, that we would cover something that is, you know, sort of indefinitely out there. That was one thought I had. And I was also, as we were having a discussion about the sort of the amounts of pressure and then earlier in my mind, I was thinking, oh, and should steroid use be a condition. And I was sort of trying, and I'm again trying to learn this stuff but I feel like it might help us to think about, well, what conditions do we practically have any ability to monitor? And it seems like the two that came to my mind in this discussion is maybe diagnosis itself and timing, but probably getting into whether people use steroids or not or certain pressures or not seems pretty unlikely that we can really have any that would be post talk anyway. And so that was my thinking and so my conditions were really around the timing, maybe a month and don't have any hard ideas about that. And then the SSNHL was mine because of the evidence around the acoustic stuff. But if the committee goes a different way for the acoustic or the acute damage, then that's fine, that's my thinking right now.

Josh Morse

So Janna I have a, a blank sheet, essentially a draft with Judy's suggestion on it that we could start from if you're ready to talk about potential conditions whenever you're ready.

Janna Friedly

Yeah, let's go ahead and do that. Let's show what they, Judy had suggested. Yeah, so I think this is a little more restrictive then, then what the discussion has been here. I'm really struggling with the timing because the evidence at least as we're presented really didn't show benefit after 14 days. And I always struggle with these conditions, similar to our previous discussion of conditions where there's the natural history of improvement within four to six weeks and how much of that is playing into, even though it's an RCT, how much of that is playing into the evidence. But I completely understand the logistics and our current healthcare system and how difficult it is to get the treatment within that time period so I'm struggling.

Tony Yen

Hey, Janna. I can just suggest changing the start treatment from 14 days of onset to 30 days of onset, given our discussion so far?

Janna Friedly

Yeah. It sounds like people would be more comfortable with that given the previous discussion, how do people feel about the treatment with steroids and the moderate to severe hearing loss? Include or not include?

Evan Oakes

I've shared my thoughts. I don't think we would include this. I'm trying to figure out how we would regulate that one at all.

Janna Friedly

Yeah. And then, of course, there's people that wouldn't be able to take steroids for a variety of reasons so then you'd have to qualify that as appropriate.

Jay Rubinstein

Just so people know, the vast majority of people are going to be, once the diagnosis is made the vast majority of people are going to be on steroids already.

Janna Friedly

Yeah.

Jay Rubinstein

And people should also know that studies of the natural history show that people with mild to moderate loss are more likely to spontaneously recover, but with profound losses are. So again, it makes sense to ramp up intensity of treatment with the degree of loss as is proposed here.

Janna Friedly

Okay. So that to me sounds like the suggestion would be to keep the moderate to severe treatment within 30 days, but to remove the also treat with steroids as that is likely not necessary?

Tony Yen

It sounds like treating with steroids is standard of care.

Janna Friedly

Yeah. Jonathan.

Jonathan Staloff

Sorry to sort of continue with these semantics. I still struggle with the timing and whether we frame it related to onset or diagnosis because I think it's perfectly feasible by the time someone gets a diagnosis, it might be 30 days past the onset of the symptoms and so I wonder if diagnosis should replace onset and if it were diagnosis, I think at least personally, I would feel more comfortable with a shorter timeframe because by the time a diagnosis is made, hopefully the ball is moving on actual treatment options, but I worry about, oh, someone's taken a month to get to see somebody they've had these symptoms and you're already past the window of being able to receive certain treatment options.

Janna Friedly

Dr. Rubinstein, did you have a comment related to that?

Jay Rubinstein

Yeah, the problem with that is that sometimes patients aren't diagnosed until months afterwards. And so the time of diag, if I diagnose someone with sudden hearing loss two months ago, it doesn't make any sense to do any intervention.

Janna Friedly

And, and uh, and Yeah, okay. Evan?

Jay Rubinstein

And all of the natural history studies are based on the event on set, the hearing loss onset.

Evan Oakes

I was kind of echo that, that I appreciate your thinking of the access, Jonathan, but I'm also realizing the evidence and so if we, so if the diagnosis happens to come later, it doesn't really change the fact of how effective hyperbaric oxygen therapy is or not. And so I think that it's the uh it's based on the onset because that's what we're noticing is when it's most effective is what I'm thinking.

Janna Friedly

Yeah.

Jonathan Staloff

Totally.

Evan Oakes

And it's unfortunate if they didn't get diagnosed until later, but it's sort of what are our treatment options at that moment that are effective?

Janna Friedly

Okay. Any other comments or suggestions or are people comfortable with this language? I think the acute acoustic trauma, I think, is still, for myself, I'll just say I think I, I was very much on the fence. I'm actually going to move to no coverage based on, because I was on the fence, but I think if, if we, if the group is still in the cover with conditions, does this language also apply to acute acoustic trauma or is there anything different that we need to consider for that condition?

Jay Rubinstein

The natural history of acute acoustic trauma is quite different from sudden sensorineural hearing loss in that the recovery tends to occur much faster.

Janna Friedly

And so if you, meaning that starting treatment within 30 days of onset wouldn't be the right time frame, it would be 14 days. Is that what you're suggesting or if?

Jay Rubinstein

To me, it's something that would have to be done a lot quicker to impact the natural history. But again, like I said earlier, the data is pretty weak, even though the rationale to me is far better. To me, it wouldn't make sense to treat somebody 30, let's put it hard in brass tacks, to me, it would not make sense to treat somebody with acute acoustic trauma 30 days after the event, regardless of what treatment we were talking about.

Janna Friedly

I may have missed this. The incidence of acute acoustic trauma, is it as rare as or uncommon as the idiopathic SSNHL. or is it more common?

Sara Kennedy

You know, I'm not sure that we included information on incidents in the report or had any for that matter, but it is typically really isolated among people who are doing firearms training, so your population at risk is at risk is smaller.

Jay Rubinstein

And in war zones it's extremely common.

Sara Kennedy

Sure.

Janna Friedly

And in war zones, the reality is that you're not going to be getting hyperbaric oxygen treatment within 14 days likely, right? If you're in a more active war zone with this trauma, I would imagine from a practical standpoint.

Jay Rubinstein

Military person might very well have access in that time frame.

Sara Kennedy

And that's where a lot of these studies came from and where military personnel who were able to be evacuated to locations where they could receive hyperbaric oxygen therapy.

Janna Friedly

Within 14 days?

Sara Kennedy

Oh, yeah. Most of the AAT cities were within hours and days um, very the evidence was.

Janna Friedly

Yeah. Okay. Okay. I guess I was more cynical about them, logistics practicality. But that's a different patient population. Any other discussion about them, the conditions for or should we, we move to a vote and then we can come back to the conditions? Does that sound reasonable, Josh?

Josh Morse

Yeah, that's okay. So your vote will be for sudden sensorineural hearing loss in these conditions and in these conditions. And we'll separate the vote from acute acoustic trauma. Is that right?

Janna Friedly

Yep.

Josh Morse

Okay. And I think Val is prepared for that?

Val Hamann

Yeah, if you all want to hop over to ttpoll. Also, Janna, do you want to, do like a cover or would you like to do like as written?

Janna Friedly

As written.

Val Hamann

Okay. Okay, and that poll is live.

Janna Friedly

Okay. And then for acute acoustic trauma, I think we need to go back to the vote itself cover with the conditions, not cover and then, and then we can do the conditions depending on the vote.

Washington State Health Care Authority

Val Hamann

So it looks like we have three for not cover and then five for cover with conditions.

Janna Friedly

Okay. And so with cover with conditions, we can go back to the screen with the conditions language. And given, I just want to, so the options are to use the same, the same criteria or given the information about the natural history time course do we do we use different coverage criteria? I'm open to suggestions.

Laurie Mischley

I mean, I think for both of them, the data supports the first 14 days and we've already compromised a little bit to meet pragmatic access goals. I don't think there's, I'm inclined to keep the criteria the same for both of them, with my thinking being that there might be a small handful of people who are requesting coverage in that 14 to 30 day window for acoustic trauma hearing loss. I don't think the number of people, the burden, the financial burden, the access burden is going to be that robust that it's worth excluding people who might have a week delaying getting to it.

Janna Friedly

Okay, any other comment, thought? So the suggestion on the table is to keep the criteria the same. Any objections to that? Okay, I'm not hearing any. So if that's the case, then we should move to a vote with, with those uh with that wording.

Val Hamann

Okay, if you want to… go back over to ttpolls.

Janna Friedly

And I do have a procedural question, and this is one I've always struggled with, so I apologize if I'm If you have voted no coverage, is it logical to vote no on this that you don't approve this or is it logical to approve the, if you know, the wording of this because you're, you're approving the, the wording or is that just?

Josh Morse

Yeah, well, that's a great question. And your vote yes or no on these conditions would typically not be a binding vote, not the final vote on your draft and we should go back and actually do two final votes on cover, cover with conditions as written, or not cover for each of these conditions, if that makes sense to you, that way when you do your final vote for cover, coverage conditions are not covered, you're voting on the conditions the situation as you still have your option to not cover.

Janna Friedly

Okay. Thank you.

Val Hamann

And we're just waiting on three. Sorry. One more response for AAT. Okay, and so we have six that approve the conditions as written and two that do not approve.

Janna Friedly

Okay.

Josh Morse

So if you're ready, when you're ready, we can go back and do two final votes on this draft.

Janna Friedly

Yep. Yes. Final votes.

Val Hamann

Okay.

Josh Morse

You know the criteria. I mean, they're the same for both, but I can reproject that before we go to the votes. It's up to you.

Janna Friedly

Sure, might as well reproject it just. Some people have it in front of them.

Josh Morse

Okay.

Val Hamann

Okay, and that vote is up. So we have seven to cover with conditions and one to cover unconditionally for sensorineural hearing loss. And that next vote is open.

Josh Morse

Yeah, and Val, can you project it? Share the. Thank you.

Val Hamann

Yes. So then we have three not to cover and three to cover with conditions.

Josh Morse

Five to three, right? Is that what you're saying?

Val Hamann

Yes.

Janna Friedly

Right.

Josh Morse

So I think we then have a couple more slides. Thank you.

Janna Friedly

Yeah, so in looking at alignment, again, there's no national coverage decision and as we've discussed, there are number of clinical practice guidelines with some variability, but they're uh consistent with coverage with conditions and the 14 versus 30 days some variability, but generally I think we're in In the realm of what has previously been decided. Okay.

Josh Morse

So that concludes hyperbaric oxygen. Thank you. Very much.

Janna Friedly

Great.

Josh Morse

Thank you, Dr. Rubinstein.

Janna Friedly

So, yes, thank you very much for your expertise. It's really very helpful to the discussion.

Jay Rubinstein

You're welcome. And I'll thank Sara for an awesome report that's really quite informative. Thank you very much.

Janna Friedly

So we, again, are a little bit ahead of schedule. We do have a half hour scheduled for a lunch break at noon, but I know our clinical expert will need to hop off for a little bit of time. Josh, would it make sense to start now, right into the next topic or to take the break now?

Josh Morse

We can do them. It's up to you. It's really up to the committee um.

Luke Wander

I was going to switch to my phone and then I can stay on my phone until about 11:50 when I need to leave and then I think I can be back. I was going to get back on my phone again after I left the facility. And I'm anticipating that'll be, you know, 60 minutes to an hour, 60 to 90 minutes later.

Josh Morse

Yeah, Janna, I think we should start now then with Dr. Chen's presentation.

Janna Friedly

Yeah, with that in mind, let's do the report and that way we'll have a little bit of time with our clinical expert to keep us moving.

Luke Wander

I'm really grateful for the flexibility. I'm sorry, team.

Janna Friedly

No, no, it happens. Absolutely. We appreciate you being here.

Val Hamann

Okay, I am promoting Chris and OHSU members.

Josh Morse

And Dr. Wander, while we're waiting for this transition, would you like to introduce yourself?

Luke Wander

Sure. Yeah. So for folks who don't know me, I'm a general internist and a diabetes epidemiologist. My clinical practice is all inpatient medicine and it's, uh, it's in veterans who are largely men and are highly enriched, especially in the inpatient population for type 2 diabetes.

Josh Morse

Thank you. Thank you very much for being here today.

Val Hamann

Okay, great. We have OHSU and we have Chris now.

Josh Morse

Great.

Christopher Chen

Sorry, Josh, are you waiting for me to present?

Josh Morse

We're ready for you, Chris. Thank you.

Christopher Chen

Okay, sorry. I'm trying to bring up.

Josh Morse

If you'd like, we can bring up the presentation. It's up to you.

Christopher Chen

Sorry, Val, can you promote my other Zoom?

Val Hamann

Yes, just did that.

Christopher Chen

Okay, thanks. Hey guys, sorry about that. I had an involuntary, um, software update this morning so still trying to recover. I will present. We're just trying to bring up presentation mode here. Okay, great. Can you guys see my screen?

Janna Friedly

Yep.

Christopher Chen

Okay, great. Well, sorry again for the technical delays. I'm Chris Chen. I work as a medical director for Medicaid here at the Health Care Authority. I'll be presenting today on continuous glucose monitors. This is a rereview from decisions in 2011 and 2018. Most of you guys are probably familiar with continuous glucose monitors, but just as a quick overview of the device, as you guys know, blood glucose monitoring is an important component of treating diabetes gives people feedback about their blood sugar levels and incidence of hypoglycemia. Previously a predominant method of measuring blood glucose is using self-monitor blood glucose systems used on Lancet, get a drop of blood, feed it into a strip and then insert it into a meter but especially over the last decade or so, continuous glucose monitors have become more prevalent in terms of usage and they estimate blood glucose levels every few minutes and can provide more detailed trend data. This information is typically collected by a sensor, I have a picture here. The sensor is typically placed on the skin because the widespread availability and usage of smartphones, sometimes that sensor feeds data directly to the smartphone via wireless communication or that can also be a receiver that separately tracks that information. There are a number of devices on the market. I just showed this from the evidence report to show there's a limited number of manufacturers producing these devices, I would say three to four manufacturers and more recently, there's also an over-the-counter option available, although the over-the-counter continuous glucose monitor, the Style Dexcom, sorry, the Dexcom Stello is marketed for people who do not have diabetes. and Abbott, Medtronic, and Dexcom make the more predominant CGMs. Sensionics makes an implantable one.

So previous HTCC decisions, CGMs were first reviewed by the program in 2011. At that time, it was covered for type 1 diabetics under the age of 19 using insulin and the conditions were those with recurrent hypoglycemia or enrolled in a clinical trial. This was broadened in 2018 to both children and adults with type 1 diabetics, as well as adults with type 2 diabetes who were, who had intensive insulin therapy regimens with poor control or recurrent hypoglycemia as well as pregnant individuals with type 1, type 2 diabetes, and gestational diabetes who are on insulin. In 2024, the Health Care Authority director selected CGMs for rereview based on published evidence that could change the original coverage determination. So the scope of our discussion today, and I'll just emphasize this slide because it can get a little bit confusing given the previous reviews in terms of what's in scope for the decision and the review. And so we're really focusing the discussion today on those for whom CGM is not currently covered, although we're also going to be recommending an update to the old language that will preserve coverage, but kind of do some wordsmithing to just clarify the decision. So the evidence review is focused on type 2 diabetics, children and adults who are not on intensive insulin regimens as well as pregnant individuals with type 2 diabetes or gestational diabetes who are not on insulin. And just also highlighting that the type 2 diabetics was structured according to intensive and non-intensive insulin regimens, whereas there was not that distinction made necessarily on the pregnant and that's because of how the previous decision was structured. So out of scope and not reviewed is the population for whom CGM is currently covered, including type 1 diabetics, type 2 diabetics on intensive insulin regimens and pregnant individuals on insulin, as well as professional CGM was the distinction between professional CGM and personal CGM being professional is typically a device that may be owned or administered by a clinic for a short period of time. These are, we're talking about personal devices that individuals use at home.

So our initial concerns for efficacy, safety, and cost were high, medium, and high respectively based on the evidence report, we have downgraded concerns about efficacy to medium and safety to low, but still potential for high cost concerns. I'm not going to get too much into the evidence report because we'll have obviously a full presentation from our, our evidence reviewers later, but the key questions were focused on effectiveness device related safety and costs and cost effectiveness. And what really stood out to us from the report that you'll hear about soon was that for adults with type 2 diabetes who are not on intensive insulin regimens we noted that there was a statistically significant reduction in A1C, but it was not clinically meaningful necessarily and so I think it was about a 0.25 difference, 0.25% difference in A1C and there was a moderate certainty of evidence there. There otherwise wasn't a difference in achieving target A1C or quality of life or evidence on reducing hypoglycemic events. If you think about the potential benefits of continuous glucose monitors, you really think do they improve diabetes control? Do they prevent harm from hypoglycemia? And a lot of people look for convenience and quality of life and there was a very small but not necessarily clinically important difference in how in control of the diabetes and there wasn't, on the preventing harm, there wasn't clear evidence on reducing the hypoglycemic events or quality of life. For children with type 2 diabetes, non-intensive insulin regimens, there weren't any RCTs identified and for pregnant individuals, the diabetes not on insulin, there weren't

an RCTs identified for type 2 diabetes and for gestational diabetes, the CGM was not associated with significantly lower A1C. Safety, no major concerns here. There weren't serious adverse events in clinical trials, people sometimes just get irritation from the sensor at the site of insertion itself. There are a number of recalls. Of CGM systems and some of them are classified as class one which means they might cause serious injury or death because theoretically, if there's a problem with the sensor, someone might become hypoglycemic, comatose, and could potentially die, so they have high classes in the recalls by the FDA, but no deaths have been reported. And then for the cost, you'll hear in the evidence report, there was just one simulated cost effectiveness study and simulations are often kind of difficult to interpret because pricing dynamics can vary so significantly between payers and purchasers. So I don't have very detailed information in terms of what our cost experience is. For Apple Health and Medicaid, we spend around $4 million a year right now on continuous glucose monitors, a little bit more for type 1 diabetics than for type 2 diabetics. For the Uniform Medical Plan across diabetic populations is about 12 million a year, but there is a rebate, a pharmacy rebate available for the uniform medical plan that reduces that to $7 million after rebate. But across our programs, the average cost per client per year for a continuous glucose monitor is about $1,000 to $2,000 and that includes the, the sensor and the receiver.

There's not a Medicare national coverage decision on this one. There is a local coverage decision that also applies to Washington state. This is broader than the current decision and so this allows for coverage of CGMs for patients with diabetes assuming the patient has received training for the device. The device is FDA approved, and so those two criteria are relatively straightforward. Treated with insulin, there's not a distinction on intensive or non-intensive insulin therapy or have a history of problematic hypoglycemia. And they also ask that patients being seen by a provider for diabetes management in six months preceding the prescription, there's not a distinction between type 1 or type 2 diabetics. A representative commercial policy, Aetna, they structure their policy according to initiation and continuation of continuous glucose monitors for initiation. And patients with diabetes using intensive insulin regimens or an insulin pump and for those under the age of 18, there are additional parameters around, sorry, so they cover CGMs for those under 18, those who have uncontrolled diabetes, and who have problematic hypoglycemia. They approve continuation on the basis of using an intensive insulin regimen or pump and have seen an improved glycemic control or decreased hypoglycemia. Using the CGM and are being assessed every six months.

So our recommendation today and again, I'll try to be as clear about communication with this as possible, but again, I'm happy to answer questions. We're recommending that we update our existing language just for clarity purposes, and that is in the top section, but the scope of the real decision today is going to be about those that are not covered under our current policy. And so we recommend continuing to cover CGM for those with type 1 diabetes or those with type 2 diabetes who are using intensive insulin therapy and are unable to achieve a target A1C despite appropriate glycemic

management plan or are suffering from recurrent severe episodes of hypoglycemia or have hypoglycemia unawareness, or covering CGM for individuals who are pregnant who have type 1 diabetes or type 2 diabetes or gestational diabetes and are on insulin, and that's largely reflective of our current decision. For the evidence report, given that there was kind of equivocal impact on efficacy and no significant evidence presented on reduction in harm with regards to hypoglycemia events or quality of life and the potentially high concerns for cost.

We recommend CGM as a non-covered benefit for individuals with type 2 diabetes who are not on insulin therapy and are on non-intensive insulin regimens except for pregnant individuals to align with the existing decision. And some of the rationale here again, kind of in terms of risk of harm and that their direct benefit, at least for the hypoglycemia side, you imagine the risk of hypoglycemia is higher for those who are on intensive insulin therapies than those who are on non-intensive insulin therapies or not on insulin therapy and non-oral hypoglycemics alone so that is our recommendation today and I'll just open up for questions.

Tony Yen

Dr. Chen, how do you define intensive insulin therapies?

Christopher Chen

Yeah, so this one. I think is maybe up for discussion for the committee. The American Diabetes Association, I believe uses three injections a day or insulin pump therapy as the definition, some people say multiple injections a day, whether multiple means two or three, I'm actually not exactly sure. I personally, from clinical experience, I honestly would probably consider some two injection a day regimens to be intensive insulin therapy, for example, if someone's on a 70-30 basal prandial mix, that seems like reasonable. I did kind of debate whether or not to recommend a definition. For you all, whether it be a combination of prandial and a basal regimen or two injections a day. Also, of course, leaving parameters for insulin pump, but want to leave that up for discussion for you all.

Janna Friedly

Jonathan, did I see your hand up or did?

Jonathan Staloff

You did and that was my precise question for Dr. Chen.

Janna Friedly

Okay. Great. Other questions from the committee? For Dr. Chen or given that? Is our clinical expert still here or did she hop off? he may have popped off. It looks like. Okay. Any other questions?

Val Hamann

Janna, it looked like she hopped back on and was in the attendees, so I am promoting her right now.

Janna Friedly

Oh, okay. Okay. Great. I just want to, in case you didn't hear, she needs to hop off um, for a bit. So if there are clinical questions from the group that would be helpful now before we have the evidence, we take a break and have the evidence report now would be your chance to ask our clinical expert questions? I don't know if it would be appropriate to ask. Yes, we can.

Luke Wander

Sure. Can you guys hear me now?

Janna Friedly

Yes, we can.

Luke Wander

Okay, good. I wondered, you know, since type 2 diabetes management is so heterogeneous, if it would be helpful at all for me to talk about how talk about CGMs in folks in this population when they ask me about it. Is that something the group would be interested in?

Laurie Mischley

Yes.

Janna Friedly

I think that would be helpful.

Luke Wander

Okay. Okay. Well, maybe I'll start there then. So, I mean, I think fundamentally For all forms of diabetes, and this includes type 2 diabetes and diabetes in pregnancy, it's really a disease of information and the, the glucose biomarker is, even in type 2 diabetes, among the most important pieces of information that's available because it impacts a lot of the care that we offer to people. And I also think it's always kind of interesting to think about the history of how we've done this in diabetes. So I'm going to talk about that for just a second. Until the 80s, we used urine and in the 80s, we moved to plasma glucose, when those monitors became available. So that's kind of the background of data and information that all this comes from. And people will often ask people with type 2 diabetes who don't meet who aren't on multiple daily injections and are taking only oral glucose lowering meds or are on diet and exercise only, they'll often ask about CGM because you see it a lot in the press. And so usually the things that I say are kind of tailored to the person, but the focus is on how you would use the CGM output to modify behavior like this can be when you eat or what you eat and when you exercise and, and when I present that to people, I talk to them about how this might help them understand Like you could switch the timing of your medicines or if you drink a milkshake and your blood sugar goes way up, you don't maybe drink a milkshake. And this can kind of help you make wrecks that are really patient-centered About lifestyle. So for example, I was seeing a patient for a diabetes research study that I'm an investigator on a couple weeks ago and she voluntarily wears a CGM. She doesn't have an indication for it. And we were talking about fart walks, you know, this idea that after you eat, you can walk and you become more insulin sensitive and she Had been watching this and watching her blood sugar go down after she eats, so this is the way that people may be using them when they're using them off-label in this space and why do I, why do I have this conversation with people in light of the equivocal evidence that was summarized? I think for a couple of reasons. So one is that these clinical trial populations, I feel like, especially in some of the clinical populations I see, the clinical trial populations are a lot more educated and not necessarily representative of folks with type 2 diabetes in general, for whom more knowledge is usually a good thing. And then the second thing is that I think some of the outcomes that we have information on are not really telling us the things that we need to know. A1C in particular. So when it was introduced, it was really a revolutionary metric because it gives you information about the information about your diabetes control over time, but it is dumb, right? It doesn't tell you anything about glycemic variability. It's just like a flat average. And glycemic variability, at least when you look in epidemiological studies, predicts bad, hard outcomes in type 2 diabetes so you know, I think. And we also know very little about like does wearing a CGM impact any of these hard outcomes in type 2 diabetes like heart disease or microvascular complications or whatever. And then last, the safety profile of the CGM is pretty good, especially in people who are not taking any meds that make their glucose lower. So all that said, when folks ask about it, that's kind of how I present the information to them because it's something they're going to have to think about whether they pay for themselves to try. And

the reason that I do it that way is because diabetes, and this includes type 2 diabetes, is super heterogeneous, and so as much as possible, philosophically, I try to put as much power of the disease management back in the hands of the person with diabetes as I as I can. And sometimes there's more than one way to get to the place that you want to in terms of blood glucose control. And so for some people in the right setting, this information is something that they can sometimes use. So that's how I have, the clinical conversation with people when they ask about it. And then for the obstetric stuff, I'm not an obstetrician but If we're talking about the outcomes that are measured, there's a similar issue in that literature too, in that it's clear in the epidemiological literature that glycemia has impacts on fetal and infant and child health, that these metrics aren't necessarily capturing if you're just looking at A1C and sort of acute postpartum outcomes So whenever I talk to people about it, I kind of caution them about all these unknowns. I think that is what I was going to say

Janna Friedly

Great. Thank you. Jonathan, do you have a question for her?

Jonathan Staloff

What's a question, I guess, more comment, which might be better, better reserved for later but um, Dr. Wander, your comment about pregnancy brought something to mind. I know there's an OBGYN on this committee as well but I was struck by seeing in the slide that A1C for pregnant individuals was the outcome of interest, whereas I feel like pregnancy is a very specific time in a person's life where A1C, I think, is probably not the most appropriate outcome for us to be considering. Especially since gestational diabetes is diagnosed typically the earliest at 24 weeks and A1C is a three month metric, which gets you to 36 weeks, so that sort of assumes that you're starting a CGM at the day of diagnosis, which I think is Pretty doubtful also I think mostly about the very, very high stakes outcomes beyond A1C associated with gestational diabetes, such as fetal macrosomia, fetal hypoglycemia, and shoulder dystocia, all of which are potentially life-threatening to the newborn, not to mention the maternal the maternal morbidity and mortality associated with gestational diabetes. So I'm looking forward to the evidence report, but I would just like caution for us to really put too much weight on the A1C for the pregnant populations.

Janna Friedly

Great. Thank you for that. Laurie?

Laurie Mischley

Yeah. For the clinical expert. I love this phrase, disease of information and so that's exactly how I use these in clinic is as an educational tool and informational means to see what's happening to your blood sugar after certain meals and certain conditions. I guess it's my impression that my wealthier patients go out and buy a Stello and they have more information and thus more education and they are more empowered and they are getting better outcomes. For me, its one of the places where I see disparities. Like the patients that can afford to buy their own Stello get better results than the patients who can't. Is that just my clinic, is that my impression, do you have the impression also and what is your opinion on that?

Luke Wander

Yeah, I think this is a really interesting question. I mean, I think there are without doubt disparities in access to CGM. Does that translate to outcomes that are clinically meaningful? I think, I think there's not a signal yet to tell us you know speaking totally frankly.

Janna Friedly

Great. Thank you. Other comments or questions from the committee and particularly for our clinical expert I know she's heading out soon? Okay, great. Well, thank you so, so much for your insight. and I know you'll be rejoining us this afternoon as you're able to um, but we really appreciate you taking the time now to answer our questions.

Luke Wander

It's my pleasure.

Janna Friedly

Okay, so I think we've had a long morning. I think before we jump to the evidence report, I do think we should take a break for lunch. We have a half an hour on the schedule for lunch. It's 11:37 now. Would people feel comfortable coming back at noon or do you want to take the entire thirty minutes.

Val Hamann

And Janna, did you want to do any public comment now or did you want to keep that at the same time?

Janna Friedly

Do we have a public comment? Do we have anyone to?

Val Hamann

I believe we have three of the six that had signed up ahead of time. Here right now. Sorry, it looks like we did have another one of those sign on. So it looks like we have four of the six here right now. One of the individuals did let us know they would be sick, so we are just waiting on one of the individuals who had pre signed up so

Janna Friedly

Okay. Okay. Well, if we do public comment now, if people are okay hanging on until that would bring us to noon and that would bring us right to the lunch hour.

Val Hamann

Okay, yeah, I will promote our first individual. So Dr. Ehrhardt. And would you like to present your slides or would you like me to do that?

Nicole Ehrhardt

Give me just a second. This was a quick onset. I didn't realize we were going to present.

Val Hamann

Yeah. No problem.

Nicole Ehrhardt

Let me grab my slides. I think it's best if I can Do them. Give me a second. I had shut down my computer, so I don't have it. I apologize.

Val Hamann

That's okay.

Nicole Ehrhardt

I am opening it up for now.

Val Hamann

And when you begin, you will have four minutes and I will give you a heads up at the 30 second mark.

Nicole Ehrhardt

Yes, I did cut I did cut uh, one or two slides this morning because I had time myself and I will be timing myself because I want to value everyone's time and everything. Let's.

Val Hamann

Sounds good.

Josh Morse

And before you begin, if you could please state if you have any conflicts and if anybody's paid for you to be here today. Thank you.

Nicole Ehrhardt

Yes, I, I have a conflict of interest slide that I added this morning so Let's see if I can share my screen.

Val Hamann

And we are seeing those.

Nicole Ehrhardt

Perfect. And I'm just starting the slideshow. Can you guys see it?

Josh Morse

Yes.

Val Hamann

Yes.

Nicole Ehrhardt

Okay, perfect. I will start them. Hello, my name is Nicole Ehrhardt. I'm one of the adult endocrinologists at the University of Washington. I have not been paid to be here today, and I'm here representing all my colleagues that were in the letter that wrote in support of increasing access for CGM in the type 2 population in those not on intensive insulin therapy and on insulin sparing agents. These are my disclosures. And as was highlighted, the American Diabetes Guidelines and other organizations are strongly saying to start CGM in type 2 early and in those non-intensive insulin therapy, additionally, to consider it strongly in those that are an insulin sparing agent, because how we see CGM is an important tool that's an individualized therapy for patients with their diabetes management. And it should have an early access for patients. And I think Dr. Thumalai, one of my colleagues, couldn't be here today, but she wanted to share one of her Harborview patients with you who'd been on just two shots of insulin a day with A1Cs greater than nine to 10 over a long period of time with no change except for receiving access to a CGM device, they went from average blood sugars of 260 to 160 in six months. And this is a much greater decrease with no change in therapy. I similarly would love to share my story of a patient, I was actually doing a semaglutide study, so 50% of people did not receive semaglutide. This patient started off with an A1C of eight. He started CGM on no insulin at all and within a week of starting his CGM, his average blood sugars decrease to 150 and by the end of the study, he'd lost 20 pounds and his average A1C was 6.8. This was with no change in medication therapy and everyone thought he'd received the semaglutide Ozempic, but it was all from the CGM.

Additionally, what I want to comment is that regionally we've been looking at CGM in patients not on an intensive therapy and a non-insulin requiring therapy and we recently completed a randomized control study with CMAR looking at in our Latino population, non-insulin requiring and basal insulin requiring patients coupled early to diabetes educations. These patients A1Cs average were 10 to begin with and only 25% of them were on basal insulin, the rest were on insulin sparing agents. As we know, education is great. We saw over a 2.5% improvement in A1C in all of our participants, but A1C increased by 0.9% more in those that were on CGM. You know, and what I'll point out is our sodium glucose co-transporter inhibitors, our DTP4 inhibitors are the effect is less than what we got from our CGM. Similarly, at Harborview, they did a study on people that were only on one or more insulin shots therapy, and they saw an absolute difference of 0.6, which is the average decrease you see from a DTP4 inhibitor. There's increasing data out there as well about it's decreasing risk of hospitalization and ER visits in those that

are not on insulin therapy and just on basal insulin therapy. And then we always want to think about the patient perspective and Just common sense. We asked our patients.

Val Hamann

30 seconds remaining.

Nicole Ehrhardt

How did they change their lifestyle and they did things like decrease their rice consumption, start eating more, read labels and they felt like CGM contributed to a healthier lifestyle. We are not even following Medicare's advice of just one insulin therapy and many states are. So we are behind providing excellence and care with our patients with CGM. So what I'm asking is decrease the burden of the paperwork, all those requirements, and just look at insulin requiring diabetes Just one shot for patients for CGM use because we have shown that it does decrease, decrease in benefit our population greatly. And we strongly encourage it be used early in all patients, even insulin sparing agents. Thank you very much for your time.

Val Hamann

Great. Thank you so much. Our next public commenter today is Dr. Panjwani. I will be promoting them. And would you like to present your slides today or would you like me to do that?

Qaashif Panjwani

You can present them. I'll just let you know. Let me go to the next slide.

Val Hamann

Okay.

Qaashif Panjwani

While the slides are getting pulled up, so my name is Qaashif Panjwani, I go by Q if there's any questions that come up but I’m an Abbott employee working on Freestyle Libre systems really a lot of the real world evidence as well as support on our clinical trial data. We can go ahead and move to the next slide. And here's just some of them.

Josh Morse

Can you please state if you have any conflicts or if you're being paid to be here today?

Qaashif Panjwani

Not being paid to be here. I'm an Abbott employee.

Josh Morse

Thank you.

Qaashif Panjwani

Here's just some of our important safety information. Next slide, please. So, uh, sorry, could you go back to the last line So within our portfolio. So within our portfolio, we have the two and three and then two plus and three plus, as you can see, the indication is for all patients with diabetes. The two plus and three plus indication did go from four with the two and the three to two and up, as well as compatibility with automated insulin delivery devices. Next slide, please. So when we look at the status quo, roughly 53% of patients met the goal of less than 7%, so there's still a large majority that are not meeting A1C goals and then when we look at resource allocation For total diabetes expenditure with the most recent economic report that came out, diabetes supply still is nowhere near the other cost factors related to diabetes management. We are seeing obviously a ton of good outcomes when we use CGM and a lot of that has to do with the lack of adherence with BGM. And so when we talk about expansion to all patients who are using insulin, for example, it really does help drive their outcomes, including A1C improvement. Then as someone mentioned earlier, improvement in glycemic variability, which is tied to a lot of macro and microvascular outcomes. Next slide. So when you talk about the ADA recommendations, I know this is already brought up in certain extent, but they are continuing to recommend along with CGM use for all patients who are using insulin. So whether they're intensively treated or just even on monobasal therapy to be able to manage their glycemic goals, but then in addition to that, because there's different AID partnerships, there's an offer or there's a recommendation for choice of device to meet the patient's needs as well as uninterrupted access to help these patients reach glycemic goals. And then for considerations on expanded recommendations, they have strengthened the level of evidence for consideration for CGM and the use of patients with adult type 2 specifically that are using non-insulin products so your oral GLP medications, as well as a recommendation around CGM use in pregnancy to help in achieving glycemic goals. Next slide, please. This was a pretty compelling study that had come out just looking at how CGM use impacts in such a short period of time when patients across the board in type two, whether they're intensively treated, basal monotherapy or non-insulin treated. One of the things that stands out is when you look at the

acute diabetes events, ER visits there was a greater reduction for non-insulin therapy type 2 adults even compared to those even on basal monotherapy so it's interesting because they do have lower events in general, but you had a greater magnitude of reduction. And within this same study as well, there was a lower uh there was a lower or greater A1C reduction with the lower baseline A1C for non-insulin group compared to basal and intensively treated populations. Next slide, please. Again, to reiterate, there's a ton of studies coming out when we talk about real world evidence.

Val Hamann

30 seconds.

Qaashif Panjwani

When patients are on basal therapy or non-insulin therapies, they are seeing significant reductions and their A1C, as well as experiencing fewer acute diabetes events. Next slide, please. And this just highlights some of the partnerships for those who are leveraging automated insulin delivery. We do have another one that did just go live with SQL Twist with the Freestyle Libre 3 Plus or are already live with TSLIN, the Omnipod 5, and then there's also partnerships and work with Medtronic globally to leverage our CGM devices for AID. And with that, I'll open it up to any questions if there's any there.

Val Hamann

We are at four minutes. Thank you. So our next commenter today is Nicole Treanor. I've promoted you.

Nicole Treanor

Okay, are you able to hear me?

Val Hamann

We are, yes. Feel free to start.

Nicole Treanor

Wonderful. To start off with, I have no disclosures, no conflicts of interest, and I am not being paid to be here. My name is Nicole Trainor. I am a registered dietitian and a certified diabetes care and education specialist. I am the program coordinator for the diabetes education program at Virginia Mason,

Washington State Health Care Authority

Franciscan Health, and I have volunteered at the state level for the Washington Coordinating Body for the Association of Diabetes Care and Education Specialists, most recently as the outgoing chair. I've worked with persons with diabetes for the past 10 years in both the outpatient primary care and endocrinology settings. And so today, rather than giving you data, I'd like to start by illustrating one example of the day in a life with a person with diabetes. This person wakes up each morning, hopefully having slept well that is, if they weren't awoken overnight with low blood sugars or waking up every few hours to go to the bathroom when blood sugars are high. They start the morning by checking their blood sugar and make a decision about what action needs to be taken, whether the sugar is too low or high. They typically take multiple medications and then they try to plan a breakfast, trying to make it a smart decision despite possibly not being able to afford healthy foods. On the way to work, they have a stressful commute or they have a stressful conversation with a teenage child that causes their blood sugar to rise. When they arrive at work, they intend to check blood sugars, but they need to rush to address an issue and forget. Then they have a coworker who offers some homemade banana bread and without thinking and without awareness of their current blood sugar, they eat two slices. Later in the day, their lunch break lunch break is delayed by an unexpected problem and they quickly eat a granola bar and rush back to work. They spend the afternoon busy on their feet and then rush out the door when the day ends, feeling a little hungry, but they're eager to get home. Midway through their drive, they start to feel shaky and a little unfocused. They can't check a blood sugar with a meter while driving, and they were already feeling hungry. So they quickly drink a 16 ounce soda and eat an old candy bar found in the glove compartment. An hour later, they finally have a moment to check blood sugar, which is near 300. Perhaps their blood sugar wasn't as low as they felt it was while driving and they overreacted with both the soda and the candy. Now they're frustrated and feeling defeated by their diabetes. They can't exercise tonight because they have to take their kids to and from activities and quickly throw together dinner. They take some evening medications and eat the first real meal of the day. Once more, when they finally remember, they check a blood sugar before bed, which is now 200, and feel frustrated to be going to bed with a blood sugar that's high.

Managing diabetes is complex and it should be the goal of all stakeholders in the healthcare system to make it easier for patients. What I have learned about diabetes is that success in managing diabetes relies largely on the knowledge and behaviors of the person with diabetes and much less on the knowledge and advice of the healthcare provider. The great benefit of CGM is that it puts the knowledge in the hands of the person with diabetes. It allows them to learn how their body responds to diet, exercise, medication, and allows them to adjust their behavior and make decisions in real time. Time and time again, I see patients improve their blood sugars because CGM helps them stay on track much better than finger stick monitoring can do. This is both because they're able to monitor more often and because they receive alerts that notify them when they're nearing high and low glucose levels. I asked the committee at a minimum to remove the requirements that patients have to check blood sugars four times daily as a qualifier for a CGM and I asked that CGM be accessible to all patients on insulin,

including once daily insulin. And not just MDI therapy. Beyond this, it has been my experience that patients on oral medications, as well as

Val Hamann

30 seconds.

Nicole Treanor

those with gestational diabetes, not on medications or just on oral medications, benefit from the use of CGM, going back to its ability to prompt behavior change. Frequently, they are able to drop A1C without the addition of more medications. Thank you for your time and consideration to expand access to CGM and helping us help those who live with diabetes.

Val Hamann

Thank you for your comments. I am promoting the next public speaker.

Alyson Blum

Hello. Good morning. My name is Alyson Blum. I am a pharmacist and a CDCES and a board certified advanced diabetes management. I work at a high-risk pregnancy clinic in Spokane, Washington. And I'm just here today to reiterate all the great things that were said but also to really focus on our pregnant patients. We have found that understanding what happens overnight and not just looking at that fasting number shows that those overnight numbers are most closely related to baby outcomes. We have always used a finger poke fasting as a surrogate marker for what happens overnight, but the reality is, is some people ride very high overnight come into range in the morning, but their babies do suffer. At our clinic, we try to get everyone on a CGM and we have noticed time and time again that every patient, regardless of whether they're on insulin or not, get that added benefit of knowing exactly what certain medications do, certain foods do, exercise, and they can immediately make changes, whether they're on insulin or not. And my perinatologist can look at baby outcomes and say, and come to me and say, what did these overnights look like and should we be driving those down harder and lower to get the better baby outcomes? We have absolutely utilized as much CGMs in this clinic as we can. Everyone that I can get it covered on, we do and patient satisfaction is astronomical. People are more compliant, they show up, and they have something that they can present to the clinic and get positive feedback with. That's all I have. If anybody has any questions for me, thank you.

Washington State Health Care Authority

Val Hamann

Great. Thank you so much. Now, we do have someone here from Dexcom, but they. It is not Greg Norman, so I am going to promote Gary and we can go from there. Gary, are you going to be presenting comments in place of Greg Norman today? That is the last public commenter that had signed up was Gary Norman, and I'm not seeing him here yet or anybody else Dexcom so. Up to you, Janna on next steps.

Janna Friedly

Well, I think we are at the top of the hour. So if we don't have any additional public comments, I would suggest that we break for lunch and then come back at 12:30.

Josh Morse

Yeah, and we can check. I think our scheduled public comment time on the agenda is technically 12:50. So at 12:50 you know we should pause and check for that additional comment if that's okay with you, Janna?

Janna Friedly

Absolutely. Yep.

Josh Morse

And we can call for people who are present today if they would like to comment at that time. Okay.

Janna Friedly

That sounds great.

Josh Morse

Okay.

Janna Friedly

Okay, so we will adjourn until 12:30 then.

Josh Morse

Thank you.

Janna Friedly

And Beth, you're going to be giving the presentation?

Beth Shaw

Yes. Yeah.

Janna Friedly

So you may have already been told that we're going to pause at 12:50. Telecom and any pump.

Beth Shaw

Mm-hmm. Okay. No, that sounds good. We'll see how far we've got through.

Janna Friedly

So I'll, I will rudely interrupt you.

Beth Shaw

That's absolutely fine.

Val Hamann

Which it does look like we have a hand raised by Greg in the attendees. I believe he is our other signed up speaker so we can get to that at 12:50. Thanks, Greg.

Beth Shaw

So I'll just wait on you, Janna. You tell me when.

Janna Friedly

Yeah, I'm just looking. It looks like we're still waiting for one more person. So I'm just giving it a moment. Oh, there we go. Okay, I think we have all of our committee members. So I think we are Okay, to go ahead and get started.

Beth Shaw

Well, hopefully you can see, you can see the presentation now. So yeah, I will get started. I'll try and keep an eye out on that 10.2, Janna to try and make sure we can hit what's the word, a logical pause. So thank you for today. I'm going to be presenting to you the continuous glucose monitoring update. We've titled this new populations, I think as Chris very clearly laid out in that agency medical director presentation, you know, this isn't CGMs for everybody, this is CGMs for those specific populations who currently do not receive coverage for CGMs under the current coverage determination for Washington. So I'm going to be presenting this today. It's a last minute stand-in for my colleague Shauna Durbin. So I will do my very best, but we'll present this to you and happy to take questions as needed. So just an acknowledgement, you know, it takes a village sometimes to do these reports. There were a lot of people involved in this. You can see the report authors there on the left-hand side, as well as other contributions across our center team, including coordinators, editors, advisors, etc. I'd also like to back now acknowledge our peer reviewers. So we have Max Rusek and Sam Weir who provided invaluable feedback on the draft, as well as the further two peer reviewers who asked to remain anonymous for this. So in terms of notice and disclosures, we don't have any specific conflicts of interest and this research was funded obviously by the Washington HTA program.

So let's move into the report in full. Very standard, so I won't go through this in detail as Sara did earlier, we will give you some background and context, but the main body of this presentation is really on the finding for the various questions. We'll touch on clinical practice guidelines and what professional associations a saying around the use of CGM for these populations and then of course we'll leave you with conclusions as you move into your deliberations. So in terms of the background. Again, just lots of kind of abbreviations here. Many of them you've already seen in kind of Chris's presentation, some of them are specific to what we do. Again, I'm not going to go through all of these, many of them I'm sure will be absolutely familiar and many of them are specific to the systematic reviews such as GRADE and risk of bias. But again, you've done this before, so we won't belabor those. This is just an overview slide really just kind of to highlight some of the complexity about glucose monitoring modalities. So you can

see in the middle that definition of CGM, you know, as Chris again very nicely explained. These are devices that automatically measure and track blood glucose. On the left hand side you can see those buckets of types of CGM. We have the intermittently scanned CGM, where patients need to manually scan those centers to get the results compared to the real-time CGM where that's a much more automatic and ongoing process. Again, as Chris stated, we're not looking at the use of CGMs in that professional or retrospective capacity where that information is used by the professional. I think we've heard very clearly from the clinical experts and the testimony you know one of the real benefits of CGM is putting that knowledge and control back with the patient, so we focused on the real-time and intermittent scan for this one. There's also two different types of CGM in terms of whether it's therapeutic or non-therapeutic. The older forms of CGM generally categorized as non-therapeutic, which really required users to verify that CGM with standard self-monitoring blood glucose before making treatment decisions, that's kind of the older model. We refer to them really today because you will see them in some of the evidence that we'll present to you. More usually nowadays that they're classified as therapeutic, which means that a patient doesn't need to confirm those findings, they can rely simply on the findings from the CGM. And obviously the comparator for most of this is the standard blood glucose monitoring, the finger prick that you all are very aware of.

So in terms of the review objective in context, we're looking here really at the effectiveness, safety, and cost effectiveness of CGM for those populations who do not currently have coverage under that 2018 Washington coverage determination. So we've passed these out in three major buckets, adults, children and pregnant people. So for adults, we're looking at adults with type 2 diabetes who are not on intensive insulin regimens, so we're talking there about people who are non-intensive insulin. We defined this for the purpose of this review as requiring one to three insulin injections or fewer than four self-monitoring blood glucose tests per day. Again, as we've touched on already, these definitions have got a lot more clinical nuance to them, but this is the definitions we've applied throughout this report. We're looking at adults with type 2 diabetes who are not on insulin but are using oral medications to help manage diabetes and we're also looking at adults who are not on insulin, nor are they using any oral medications, so really that diet lifestyle approach. We're looking at the same groups of people for children, so those three groups, non-intensive insulin, oral diabetic medication, neither of the above. And then for people in pregnancy, we're looking at people both with type 2 diabetes or with gestational diabetes, again, people who are not using insulin during that phase of their diabetes.

So I'll quickly run through the methods. As mentioned, we looked at both the effectiveness of CGMs as well as the device related harms. We looked at whether there was any evidence on differential effectiveness of or harms, you know, were any patients more likely to benefit or less likely to benefit than others. And we also look for information on the cost effectiveness of CGMs or any information on cost or resource use that might be related to the use of CGMs. As well as those very evidence-focused questions, we looked at ongoing studies so that you can see kind of the type of research that's being

conducted in this area at the moment. We've looked at those clinical practice guideline recommendations, you know, what are they recommending for use of CGM, and also on select payer criteria. So running through our PICOs, again, as I've stated, the populations were very specific for this. So adults and children with type 2 diabetes bucketed into those three groups, non-intensive insulin use, no insulin but oral medications, and neither, and then those two groups during pregnancy, type 2 diabetes or gestational diabetes with no insulin use. In terms of the interventions, we saw the list earlier. You know, there's a number of these interventions and the changing, you know, there's new kind of updates of existing CGMs as, new CGMs coming out all the time, so we stuck for this review, to the FDA approved real-time and intermittently scanned CGMs. In terms of comparators, we've talked about self-monitoring blood glucose, we were definitely looking for that. We were also looking for that attention or kind of wait list control, so people having delayed access to CGM, looking at blinded or sham CGM, as well as other type of routine lab monitoring or indeed whatever classifies as usual care. We'll talk about the outcomes on the next slide, but in terms of the study designs, for those questions on effectiveness and harm, we really limited this report to randomized controlled trials and as you saw with the HBOT review earlier, in order to maximize their applicability to the US context, we limited those two countries studies, studies that have been conducted in countries that classify as very high on the United Nations High Development Index. For our key question four, which is looking at cost effectiveness and resource use, we looked at formal studies, both the simulation cost effectiveness one that Chris mentioned earlier, but also resource use and again, to maximize applicability to the US context, we limited that to studies conducted in the US, and only those studies in the last five years.

So outcomes. So we've got a reasonable list here of outcomes, both related to effectiveness and harms. So the main things around effectiveness really do focus on that HbA1C level so we've got change in HbA1C, whether people achieved their targets that they'd been set for those HbA1C levels and whether people maintained those targets using CGM generally compared with self-monitoring. We looked at people, whether people were experiencing, experiencing acute episodes of hypoglycemia that required intervention, so that really kind of serious level of hypoglycemia. We looked at quality of life for all the reasons that we've heard about, you know, what's actually the impact on people's lives, you know, beyond just the impact of the HbA1C change. And then in terms of safety and the broader issues, we looked at mortality specifically for pregnancy we looked at perinatal mortality and severe perinatal morbidity. And Jonathan, I think you alluded to before you know about the serious outcomes that can be, can be seen in pregnancy for people with type 2 or gestational diabetes. In terms of other safety, we've really focused on those related to the device itself as well as cost effectiveness and resource use and you'll see kind of lots of information about these as we move through. I won't go into detail about the risk of bias assessment, but as ever, we've looked at each of these studies and looked at their risk of bias, where we assess it as being low risk of bias, that study has been well conducted, it's been well reported, and they've really taken steps to try and mitigate the potential for risk. Where we assess a study as being at high risk of bias, that really kind of breaks into concerns about how credible, how believable are those findings. We'll talk about them generally, but you'll also see in the GRADE tables the

specific reasons for why we've applied risk of bias concerns in that GRADE rating. And so talking of the GRADE rating, again, I won't remind you of the details, but for the outcomes that we did grade, we looked at change HbA1C, we looked at achieving or maintaining those target HbA1C levels, we graded quality of life as well as the severe perinatal morbidity and mortality and cost effectiveness. So again, just a description there, high means we're very confident, we don't expect that any new research would change ultimately our understanding, when we're in the low to very low any new research is likely to kind of change our understanding of that specific finding.

Just a reminder of the public consultation as well, this was available for public comment and peer review earlier this year. We had those four peer as well as 22 comments from the public so you can see all those responded to and that's available online. We made appropriate revisions, so improved our terminology, we improved clarity and again it's the final report that we're talking to today. I just wanted to highlight one issue. We were, obviously people said, you know, here's some references that I think might be relevant or useful to the report we've checked all of those against our inclusion criteria. But just to note that there were a couple of eligible studies that were beyond are cut off so we've not formally included them in the review because we've not done a full systematic review. So there could be other studies that have also been published since our cutoff date, but because they've already been cited today and they were specifically highlighted in that public comment, we're going to kind of walk you through what those studies say and make a best judgment about whether we think they would ultimately change the findings that we have in the report. A major caveat with those new studies, we have not done that formal risk of bias so we are not going to be able to say to you whether we think that study is believable and whether it's what the risk of bias is and we've not incorporated it into our GRADE ratings. But it gives you, you know, these are key studies that came up time and time again so we didn't want to just kind of ignore them and, and feel, you know, we wanted to give you as big a picture as possible.

So let's move into the evidence findings. So this is our standard study flow. The main thing that I think you should take note of is that information in the red box. We went through nearly 8,000 studies, so a lot to get to these, but ultimately, in the final report, we've included 22 randomized controlled trials. These were reported in 35 publications. We've included two stories that talk about economics, costs or healthcare resources, one of which is a formal health economic modeling study, the other is very much like a cost budget analysis before and after and we've also looked at 13 clinical practice guidelines. So there's a lot of information in this report, so we're really just going to try and touch on those kind of high points for you and allow you to have the discussion as needed around this.

So our first question is, I think, the one that we always start with, you know, how effective is CGM compared with self-monitoring or other forms? So we just wanted to kind of give you the bottom line here, you know, really kind of call out the headlines and then we'll go through some of the detail. So in

terms of the populations that we found that did have eligible randomized control trials, we found 18 randomized controlled trials that looked in that population of adults with type 2 diabetes who are not on that intensive insulin. Of those seven were in people who were using insulin to a non-insensitive level, so one to three injections a day, six are in people who are on oral medications only, but no insulin use, and then we have five in what we're kind of calling a mixed diabetes regimens. These are populations where they really recruited anybody. They could be using insulin, they could not be using insulin, they could be using oral medications as well as insulin or not, but there wasn't enough signal for us to say these are intensive users, so it's really very much a mixed population and we didn't want to lose that information for you, but what it means is that it's a little bit more difficult to interpret that against whether using insulin or not, whether using oral diabetic medications or not, so they're in there. We found four randomized trials on the use of CGM in people during pregnancy with gestational diabetes who are not on insulin. And then we also found some gaps in the evidence. So we did not find any eligible randomized controlled trials in that group of adults with type 2 diabetes who are not on insulin or using oral diabetic medication, so really people just managing type 2 with diet, exercise, no randomized studies there. We didn't find any eligible randomized control trials in children at all. So any of those populations, there were no randomized controlled trials for children and we didn't find any eligible RCTs for people during pregnancy who've got type 2 diabetes who are not using insulin. So right from the bat, there are some key gaps in the evidence there for this particular update.

So just give you the bottom line, I've got three minutes and I think we can do this for the 12:50, this kind of hopefully sets up the report nicely. We just wanted to focus on what was our primary outcome, which was that change in HbA1C. So if we're looking at adults with type 2 diabetes who are using insulin but not to that intensive. We found that the use of CGMs did result in a small, but potentially not clinically meaningful reduction in HbA1C when compared with standard blood monitoring regimes. It was small, so not clinically meaningful, we can talk about that in more detail later, but it was a statistically significant reduction. When compared with non-CGM controls and we've assigned that a moderate certainty of evidence, so we're reasonably confident in that finding. When we look at the next group down, so this is adults with type 2 diabetes who are not on insulin, but they're using oral medications. We didn't really find any consistent difference in that change in HbA1C from baseline between CGM a non-CGM controls. And for that group of adults who are not using insulin nor using oral medications, that's one of the evidence gaps, no eligible randomized When we look at the next group down, so this is adults with type 2 diabetes who are not on insulin, but they're using oral medications. We didn't really find any consistent difference in that change in HbA1C from baseline between CGM a non-CGM controls. And for that group of adults who are not using insulin nor using oral medications, that's one of the evidence gaps, no eligible randomized control trials. And when we look in that population with mixed diabetes regimens, so kind of a bit of everything, not surprisingly, we really didn't see any consistent differences. They're probably due to that kind of heterogeneity of those populations and we assign that very low certainty of evidence. So for other than that first one where we've got moderate, the next two for adults where we've got trials are in that kind of more uncertain area, low to very low certainty of

evidence. And moving on to our next group of populations, as mentioned, two big evidence gaps here. No randomized controlled trials in children, regardless of what the diabetes medication was or not. No studies in pregnant people with type 2 diabetes who are not using insulin. And then in that pregnant population with gestational diabetes, again, we kind of saw that CGM use really wasn't associated with a significantly lower HbA1C at the end of pregnancy so really looking at that four to 16 weeks of follow up when compared with non-CGM controls. Again, lots of uncertainty around that and I think we've already heard people kind of speculating why HbA1C may or may not change in that shorter period during pregnancy. So that's the headline. It's 12:50 Janna so maybe this is before I go into the details, I think this is a perfect pause.

Janna Friedly

That was very well timed. I'm impressed. That's great.

Val Hamann

Great. So we will jump over to public comment and we will start with our last pre-signed up commenter, Greg Norman.

Josh Morse

And Val, have you asked, have we asked if there are additional people who wish to speak today?

Val Hamann

We have not. So if you would like to speak today, please do so by indicating raising your hand, please. And then Greg, just as a reminder, you will have four minutes and feel free to start when you are available and please identify if anybody has paid you to speak today.

Greg Norman

Great, thanks. My name is Greg Norman. I'm the Director of Health Economics and Outcomes Research at Dexcom. So I'm an employee of Dexcom. And thanks for giving me the time to an opportunity to comment today. Two areas I want to address. First is the evidence for coverage of people with type 2 diabetes on diabetes medications other than insulin and the second is on CGM coverage for women with gestational diabetes not on insulin. This might have already been mentioned, but the American Diabetes Association has updated the guidelines for use of CGM reflecting evolving evidence. The 2025 standards of care now recommend the consideration of real-time CGM for adults with type 2 diabetes who are treated with glucose lowering medications other than insulin. And since the updated ADA standards of

care, two of the largest PBMs in the US now provide coverage for CGM for all people with diabetes, indicating that commercial payers are starting to recognize that CGM benefits people with diabetes, not on insulin. So the Washington HTA meta-analysis of RCTs of people with type 2 diabetes on oral medications but not insulin, did not find a statistically significant reduction in A1C favoring CGM. But a similar meta-analysis was published in 2024 by Ferreria and colleagues and included six RCTs, three of which are among the five studies in the Washington HTA meta-analysis. This meta-analysis did find a statistically significant 0.38 change in A1C favoring CGM. So I recommend reviewing the Ferreria meta-analysis to compare findings with the Washington HTA. One study that was included in the Washington HTA but not included in the Ferreria meta-analysis was the GLIMPSE study from Singapore. The GLIMPSE study was excluded from the Washington HCA analysis and a sensitivity analysis and then the findings were statistically significant and favored CGM. The study technically should not have been included in the meta-analysis because it did not meet the study inclusion criteria since 30% of the study group was using basal insulin. So I'm not sure. I mean, just wanted to point that out. I mean, on the other hand, I know this is beyond the, the inclusion period, but there was a study published in September 24, so 2024, so just after by Dr. Lao. They randomized 105 people with type 2 not on insulin to either CGM with telemonitoring or to enhance usual care. The results favored CGM with a 0.65 greater reduction in A1C compared to the enhanced usual care group. So my point is that slightly different included studies, example, not including the GLIMPSE study and including the study by Lao, I think the Washington HTA meta-analysis would likely have favored CGM for A1C reduction for people with type 2 diabetes on oral medication, but on insulin. And then regarding gestational diabetes, it was noted in the HTA report that Oregon Medicaid limits CGM coverage for individuals with gestational diabetes to those using insulin. However, it's important to note that the majority of state Medicaid programs such as states of California, New York, Texas, they do extend CGM coverage to all individuals with gestational diabetes, regardless of insulin use. So there are 26 states that collectively account for more than 70% of the annual live births in the US. So this substantial coverage reflects the growing potential for more improved and equitable maternal and neonatal outcomes across a significant portion of the population, and there is an abundance of evidence that CGM improves glycemic control in women experiencing GDM, better time in range, better detection of hypo.

Val Hamann

30 seconds.

Greg Norman

And hyperglycemic events. So my suggestion would be to consider evidence from studies demonstrating The value of CGM in pregnancy for women with type 1 and type 2 diabetes and women with gestational diabetes using insulin are very likely, those studies will generalize to women with GDM not using insulin because I think it'll be it would be really hard to do a properly powered large enough clinical trial to see

adverse events like maternal and neonatal outcomes for women with GDM not on insulin. So that evidence may never be there. I'll stop there.

Val Hamann

And that concludes the four minutes. Thank you so much.

Greg Norman

Thanks.

Val Hamann

And I will promote Dr. Jones. Is there anybody else currently in the attendees who has not spoken yet today that wishes to provide comment? If so, please raise your hand.

Ty Jones

Hi, Dr. Jones at Regence once more. Thanks for having me again. Thank you. I wanted to comment and compliment an area that probably doesn't receive that much attention. Dr. Chen, the language formatting and structure of your proposed determination, is excellent. Clarity in these determinations is so important to those who are administering these determinations. And also for the patients who looked them up to try to understand their coverage and for the clinicians who are trying to obtain these services for their patients. Now, imagine one that is not clear and having two of those parties try to reach an understanding of what they mean. So speaking as someone who would be responsible for administering this determination, I want to strongly endorse Dr. Chen's recommended format as opposed to potentially adding lines to the 2018 version. His revision would eliminate the difficulty we and members experienced regarding the HTCC's intent with the current version and addresses potential conflicts with Section 1557 of the Affordable Care Act by removing some of the age determinations. There is one area where one further definition would be helpful, administering and interpreting this criteria. I note in the proposed language, the terms non-intensive insulin regimen and intensive insulin regimens are included in the proposed determination and would ultimately dictate coverage in certain circumstances. It would be helpful to define them in the limitations of coverage what constitutes an intensive insulin regimen. I couldn't tell you what that means off the top of my head, but I have ideas. So that could be a statement from an endocrinologist stating the member is using an intensive insulin regimen, it could be, or I guess I'm asking would it? Would it be documentation of a certain amount of daily insulin injections per day? Could it be use of a pump? Use of any insulin over simple basal injection? So that may cause some confusion so please help define that in the final determination and provide some defining criteria. So thank you, Dr. Chen and the HTCC.

Washington State Health Care Authority

Val Hamann

Great, thank you. And it does not look like we have any other attendees who've indicated they would like to speak today.

Janna Friedly

Great. Thank you. So I think we can turn it back to Beth. You're muted.

Beth Shaw

Yes, I am muted. Thank you. Hopefully you can see everything now as well.

Janna Friedly

Yep.

Beth Shaw

Perfect. So yeah, now we'll dive into a little bit more of the detail and go through some of those outcomes beyond just the change in HbA1C. So we'll start with adults. So again, starting with that population of adults with type 2 diabetes using non-intensive insulin regimens, so one to three injections per day. We found seven randomized controlled trials in 15 publications. A total sample size across those seven randomized controlled trials was just over 800 participants and the follow-up range from 12 to 52 weeks. Overall, the risk of bias for these studies was kind of low to moderate. And just as a general kind of overview of why we had some concerns about risk of bias, in general, it was around blinding. As you can imagine you know it's a lot more difficult to blind people against CGM versus self-monitoring of blood clues, blood glucose and there were some concerns around you know as you'd imagine, you know, like manufacturer funding. So just as a broad overview, those are some of the, the main reasons you'll see some of the more specific reasons in the GRADE tables. And again, just as a bit of background to those randomized controlled trials, in terms of the baseline means of the patients involved in those studies, they were older, you know, 51 to 61 and a half years, the baseline HbA1C was around 8.2 to 9.7% at baseline. Significant duration of diabetes from around 13 to just under 19 years, and of those two studies, sorry, of those seven, two included participants in the US. In terms of the different types of CGM that were evaluated, six of them looked at that real-time CGM, of which three were those older style kind of non-therapeutic devices that are no longer available, and one evaluated the use of intermittent scanned CGM. All of these studies use continuous glucose monitoring throughout the study. You'll see in some of the later studies people maybe used them for a week on and then maybe three

weeks off. You know, in this group of studies, they did not do that, they were given the CGM and they used that as and when throughout the study period. And then each of these studies was comparing that with the self-monitoring blood glucose. In terms of the diabetes regimens, obviously these were all people who were using insulin, the minimum was around one to two injections of basal insulin per day and then the maximum was that NDI of basal and prandial insulin, so those multiple daily injections of insulin. Most of the participants in these studies as well were also using oral diabetes medications, so thinking things like metformin, the sulfonylurea, or GLP-1s like things like semaglutide, so there were other things in the treatment regimens beyond insulin alone.

So what did we find? Well, as mentioned already, from those seven randomized controlled trials the use of CGM did result in a small but statistically significant reduction in HbA1C. So when we did the meta-analysis, this was, um, you achieved a 0.27% decrease compared with self-monitoring when compared with, yeah, self-monitoring. The confidence intervals range from 0.46 to 0 point null to 8. And depending on where you think clinical significance lies, and there is some controversy about that, you can determine whether that's clinically meaningful, we went with a 0.5% reduction, that's a clinically meaningful difference that's often cited in the literature. So for example, kind of my alma mater UK is NICE use a 0.5% as being a clinically meaningful difference, other authorities such as the FDA have used a 0.3 reduction. So you can see if it's 0.5 it's not a meaningful change, it's statistically significant, but it may not be clinically meaningful if you apply a 0.5. If you apply a 0.3, which is a less conservative one you may feel that that is a clinically meaningful difference. We assess that as being moderate, we downgraded just for that risk of bias because of a potential risk for selective bias, as well as that funding related conflict of interest, so relatively certain for that. We really didn't see any difference between CGM or self-monitoring blood glucose group in the proportion of people who achieved target HbA1C levels. So we had 7% versus 7.5%, no statistically significant difference. It was only in the one randomized controlled trial and we downgraded that for two levels, because of imprecision, so there were wide confidence intervals, as well as indirectness, this was one of the studies that used that non-therapeutic or the older style CGM. And this is the meta-analysis that we looked at for that. So you can see all the information on here and then at the bottom that minus 0.27. So that's the meta-analysis showing you that kind of drop of around 0.3%, it could be as high as 0.46%, or it could be as low as a 0.08% reduction.

When we look at quality of life, again, looking at both diabetes related quality of life as well as general quality of life, there really wasn't any clear association between CGM and improved quality of life. It was mixed, so either studies showed no difference or they did show improvements in quality of life. And even where they were statistically significant, it was actually really unclear whether those differences were clinically meaningful, were they big enough to actually have a meaningful impact on somebody's life. What we did see in general was that follow-up scores, regardless of what group you were in, were generally indicative of low diabetes distress levels and high treatment related satisfaction. So across the board, even if there was no difference, they were generally high, so people weren't experiencing high

levels of diabetes distress or dissatisfaction with treatment. Both of these findings we rated as having low certainty of evidence, so again, some uncertainty around this primarily for things like risk of bias, that inconsistency we saw mixed findings, as well as some indirectness with use of non-therapeutic CGMs. And finally in this group, we have some other outcomes where we didn't apply GRADE to, but these are important outcomes. Five of those randomized controlled trials reported on that serious event, you know, those serious episodes of hypoglycemia. Overall, there were very low event rates across these five randomized control trials and there was no between group significant testing. So we can report the data, but there wasn't any formal statistical testing. So across 700 participants in those five randomized control trials, we saw six hypoglycemic events that required intervention. No events were directly attributed to CGM use, so low event rate and no clear link to use of CGMs. And in terms of mortality, this was reported in two randomized control trials and again, I think as you'd expect, very low event rates and again, no formal statistical testing. There was one death that was reported due to myocardial infarction in a trial of 300 participants and the event or across those 300 participants in the two studies. And that event again that death was not directly attributed to CGM use.

So moving on now to the next group of adults with type 2 diabetes, so this is the group of people using the oral medications only and not insulin use. So we found six randomized controlled trials in eight publications, just a slightly smaller number here, 560 participants and again, a follow-up range of 12 to 52 weeks. Risk of bias was a little bit more mixed here, with two each in the low, moderate, and high categories. Demographics actually reasonably similar in terms of age that kind of older population as you probably expect with type 2, so 50 to kind of 60 years. Slightly lower baseline HbA1C, again, you'd probably expect that 6.6 to 8.7. Slightly shorter duration of diabetes, 9.2 to 13.9 years. And only one of these trials included US participants. Again, in terms of the actual CGM use, a range of mortalities, a bit more varied here with three randomized controlled trials of real time and three with that intermittently scanned. Again, a bit more mixed level of use with duration. So two randomized controlled trials had that continuous and ongoing use of CGMs and then there were four randomized controlled trials where actually people were using CGM for less than 50% of that study duration, so those are their examples where people might be using it for a week on and then maybe the rest of the, you know, the three weeks out of the month they're not using CGM, so a little bit more sporadic use there. And again, a wider range of comparators here with the majority though being compared to self-monitoring blood glucose. Again, in terms of the, apologies this, this is the wrong slide here, so these are oral medications only, so they're not using insulin, in this group. But again, you can see in the report all the different oral medications that are being used, the main suspects, metformin, sulfonylureas, and the GLP-1s.

So what did we find for this? Well, again, that primary outcome in terms of change in HbA1C from those six randomized controlled trials, you've already heard this kind of bottom line, there was no real consistent difference in change. In our meta-analysis, we found a reduction of 0.2, .18%, but it was not statistically significant crossing that line of no effect so it could be as low as 0.45, it could be as high as an

increase of 0.09. We've already heard that there was some uncertainty around this, you know, if the GLiMPSE trial was removed, that finding then did become statistically significant and that is really reflected in that low certainty of evidence. So I think, you know, we've just heard about you know maybe that trials in there or not, we can look at that in more detail, but I think what we are seeing is that this finding is less stable than the other one. So if it does differ by which studies are in and you know the exact inclusion exclusion, that does suggest a little bit more uncertainty in this area which is reflected in that certainty of evidence. We've got less certainty of that because of that inconsistency, you know, removing the GLiMPSE trial gives us a slightly different answer and again, for risk of bias. We just had the one randomized controlled trial that looked at that achievement of target HbA1C no significant difference between the groups of people who achieved those targets of 7., 7% or 7.5%. Lots of uncertainty here though because of risk of bias, indirectness, that's the they didn't use the CGM for the complete study period as well as things like imprecision in this case because of a smaller study size. And again, you can see here that meta-analysis where you can see at that bottom that black diamond, no statistically significant between the groups. So again, carrying on with this, looking at quality of life, both for diabetes related quality of life and that general health related quality of life. Again, no clear association between the use of CGMs and diabetes or general quality of life. Really mixed findings here and again, where they were statistically significant, it really wasn't clear whether they were clinically meaningful. So lots of uncertainty in these findings for many different reasons, including risk of bias, imprecision, as well as indirectness, you know, how applicable is this to the wider population who might use CGM. And then just following up with these non-GRADE outcomes similarly to the other group of people, very low event rates of that serious hyperglycemic events. Two events across 440 participants and again neither of those events were attributed to CGM use and there was no mortality reported in any of these randomized controlled trials.

We wanted to provide you kind of with the breaking news, the evidence update. So as mentioned, we did get some studies highlighted to us on numerous occasions that had been published since our study cutoff. So this is a randomized control trial that was published in October of 2025. I think our searches were conducted in September, so we just missed out on this one. Again, we've not done a formal risk of bias, but we just wanted to highlight some of the key features. This is a 12-week randomized controlled trial looking at CGM with enhanced usual care in 105 adults with type 2 diabetes who are not on insulin therapy and the vast majority of these were on at least one oral, oral medication. The mean change in difference was not was not significantly different between the groups, but it was significantly lower with CGM when adjusted for those baseline HbA1C levels. So again, the higher your baseline HbA1C level in this study, the more likely you were to have a meaningful reduction when using CGM, again, we've heard that from the expert and the public testimony. What we did find is that when we added that to the meta-analysis, it really didn't change our findings. So on this next slide, the top graph, you can see the original results and then on the second graph with that red, that new study highlighted from the public comment, you can see it's moving a little bit to the left so it's kind of trending in the right direction, but it

still remains non-statistically significant at this point and again, depending on your view of what is clinically meaningful, whether it's 0.3% or 0.5, is that clinically meaningful or not?

One of our big evidence gaps here in the next population, we didn't find any eligible randomized controlled trials in adults with type 2 who weren't using insulin or oral diabetic medications. Here you can see this is the kind of that mixed group of people. So, you know, mixed diabetes regimens, people using insulin with or without oral medications, some people using oral medications alone, so really, this is more kind of more for information we couldn't find a clear reason to exclude these. So five randomized controlled trials, 450 people with again that follow-up range of 12 to 52 weeks, again, it crosses the low to high in terms of risk of bias. You can see the baseline means, again, that kind of older population. HbA1C ranging from 7.8 to 11.5 at baseline. No real consistent information on diabetes duration and again, three trials included people from the US. Again, a range of CGM use kind of across modalities, the duration of use as well as comparators. And then in terms of those diabetes regimens, this is you know the title says it, it's a mixed group, so it's mostly non-intensive insulin along with oral diabetes medications and in general, what we didn't see with these studies, what we'd hoped is that some of those outcomes might have been stratified by the treatment regimen to give us a bit more kind of insight into who might benefit most, we didn't see those in these trials. So as you might expect, because of the heterogeneity of the clinical populations we saw heterogeneity in the findings for change in HbA1C. So no real consistency, there were no between group differences at final study follow-up. What we did see is that in the study that had the higher proportion of insulin users, CGM was associated with a statistically and clinical, clinically greater reduction, as again, I think you'd anticipate, you know, with that people in that kind of higher risk group. Each of the CGM groups experienced a clinically meaningful reduction. So kind of about 0.8% to minus 5.2 compared with only three of the five control groups. But again, really mixed here and that's reflected in that very low certainty of evidence. None of the studies looked at that achievement and target ABA1C. And both for the two different types of quality of life, no real difference in quality of life between these groups. And again, lots of uncertainty here for things like indirectness, imprecisions, as well as some other reasons that you can see cited in that GRADE table. And just these final very important outcomes that we didn't GRADE, again, for serious hyperglycemic events, very low event, event rates with four events across 206 participants. Again, none of these attributed to CGM use. And in the single randomized controlled trial that reported mortality, there were five deaths among these 141 participants over a year. The causes of death weren't reported and again none were directly attributed to the use of CGM.

Moving into children. As stated before, a bigger evidence gap here, no randomized controlled trials that met our criteria looking at the use of CGM in children with type 2 diabetes regardless of insulin use, oral medication use, or no use.

So use of CGMs during pregnancy. Again, a gap here we didn't identify any eligible randomized controlled trials for people with type 2 diabetes during pregnancy who weren't using insulin. But for people with gestational diabetes, we identified four randomized controlled trials, just over 300 people. Again, a follow-up range shorter for all the reasons we know of four to 16 weeks and again, one low, one moderate and two high risk of bias. You can see the demographics here on the left hand side. I'll let you read those gestational age 22 to 34 weeks maternal age around 30 to 35 years, and again, in HbA1C around 5% to 6%. Each of these participants were newly diagnosed, as you'd expect. CGM use, again mixed really across modalities, duration of use and the comparators. And then certainly within these trials, some participants in each of the studies did receive insulin due to rising blood glucose levels or risk of hyperglycemia. In terms of that new insulin use this ranged from 17.4% to around a third at final follow-up. So in terms of changing HbA1C, again, we really didn't see any association between the use of CGM with a significant lower HbA1C. We assigned that a low certainty of evidence, so lots of uncertainty here. And then none of the studies that we included reported achievement of target HbA1C levels which may or may not be as appropriate for this population and neither was quality of life reported. We did GRADE for this group of people the outcome of severe perinatal morbidity and mortality. And really, we didn't see any significant between group differences in the incidence of those severe perinatal outcomes. There were very few severe adverse events and there were no statistically significant between groups in most of the reported outcomes. so that's things like large gestational age, preterm birth, we heard about shoulder dystocia earlier, as well as things like unplanned caesarean delivery. However, the results are macrosomia were a little bit more mixed, so we did see a less clear pattern for that particular outcome. For this, again, because of all the uncertainty around these very low event rates. We assign this as a very low certainty of evidence, so again you know it's not a very clear picture for this. For those other outcomes, no randomized controlled trials in this population reported the severe hyperglycemic events and no randomized controlled trials reported mortality.

So let's look at the device related safety. 12 of the 22 randomized controlled trials looked at device-related safety and as Chris mentioned earlier, all of the events were really related to that sensor insertion site related symptoms. So we're thinking things like rash, pain, infection, and the majority of those symptoms were mild to moderate and they usually resolved through things like topical treatment or by moving the sensor to another part of the body. Very few device discontinuations or study withdrawals were reported directly associated with those CGM issues. So most people continued even if they did experience these mild to moderate events and no observes serious advance, serious adverse events were attributed to the use of CGM. We also looked at device-related harms in the FDA's MAUDE Database, so this is the manufacturer and user facility device experience database where people are encouraged to submit these reports. One of the major caveats of this is it's a voluntary database. Inherently there's kind of selection bias in this but we actually saw very similar kind of reported adverse events related to the use of CGMs, so again, mostly insertion site related symptoms. There are some various sensor malfunctions, so thinking about things like premature detachment, failure to connect with the receiver, as well as observations around inaccurate blood glucose readings with all the implications

that that might have for people. Two deaths were reported in this database related to CGM use, but it's really unclear if they were directly related to CGM use these are not fully documented case reports, these are really very high level and very difficult to determine causality using this information. What we did note, though, is that there have been some device recalls in the not so distant, uh, past and there's five eligible open recalls of CGM systems reported in the FDA medical device recalls database. These exclude recalls for discontinued devices, so all of these at the time of the report were available within the US and we excluded any that had been posted more than two years ago without resolution, so these are active and ongoing. So in the class one medical recall device that's categorized as the most serious, there were three recalls related to extreme heat and fire risk from rechargeable lithium-ion batteries in handheld reader devices. And again, that potential for inaccurately high blood glue, glucose readings from certain sensors which could increase the risk of hypoglycemia with that too much insulin administered. Similarly, in the class two, that next level down, again, the potential for incorrect readings due to overly thick layers on some sensors that can result in people misreading the findings of the censor so resulting potentially in either under or over administration of insulin. It's also worth noting that in the last month as well there's also been a letter issued, I think, by the FDA noting kind of manufacturer quality concerns within factories. So, you know, this is again, an area that's moving.

So look at differential effectiveness and safety. We'd looked at a range of subgroups of interest, s you can see those on the right hand side so you know do effects differ by age? Do they differ by morbidity status as well as severity of diabetes or adherence? Really changing HbA1C was the only outcome where they really explored differences by these subgroups and they were reported in six randomized controlled trials of adults with type 2 diabetes. And it really didn't tell us much, there was really no strong or consistent differences and the only kind of features that were assessed in terms of subgroups were age, gender or sex, race or ethnicity, baseline HbA1C or adherence and really no clear signal about any one of those really driving differential effectiveness or safety. None of the other subgroups of interest were explored in the randomized controlled trials that we included in this update.

Moving on to cost and cost effectiveness, we identified two eligible studies reporting economic outcomes on the use of CGM with that specific perspective of that of the US. So Frank as the primary author in 2024, published a cost effectiveness analysis in adults with type 2 diabetes who were using basal Insulin, they did a micro simulation model, modeling using 10,000 simulated patients and they were looking at the use of intermittently scanned CGM versus self-monitoring blood glucose. And it's worth noting that when they talk about intermittently scanned, they really focused on the Freestyle Libre system, so it's just that single CGM model that they used. This analysis was conducted from a Medicaid perspective and they made certain assumptions that you can see here around both self-monitoring, blood glucose, or one test strip and that's it per day. Versus CGM, one test strip and one set per week, etc. We assess that as being moderate risk of bias and that is the finding that we graded and you'll see that on the next slide. We also included kind of one cost analysis where really they just looked

at, you know, what were the resource uses of people when they were doing self-monitoring blood glucose and did that change after CGMs were introduced. So this was a 12-month retrospective analysis of commercial and Medicaid claims from 2018 through to 2019. And really, they just compared the cost before CGM and after CGM. And we assess that as being at high risk of bias. As mentioned, we have focused or we prioritized GRADE only for that cost effectiveness analysis. And what the findings were, were that over a 10-year time horizon from that Medicaid perspective, CGM, and specifically Freestyle Libre, was dominant to self-monitoring blood glue, blood glucose, which meant that there were more QALYs for people or quality adjusted life years for people with CGM, there were more life years gained and it was at a lower cost when compared with self-monitoring blood glucose for people with type 2 on basal insulin. We assess that as being a moderate certainty of evidence and we downgraded really just for risk of bias because of the role of the funder in the study publication. In the cost finding study, so the Kerr et al., paper from 2023, what they found was that actually all cost per patient per year costs were significantly lower with self-monitoring blood glucose versus CGMs for adults with type 2 or mixed diabetes regimens. And you can see there the cost, you know, $19,500 versus $20,500. What they noticed was that the difference in costs were primarily driven by lower pharmacy costs and fewer outpatient for people using self-monitoring blood glucose and there were no between group differences between CGM or self-monitoring for people in terms of emergency department visits or hospitalizations. And again, we've seen that study that's been referred to at least twice today, which is that Garg et al., study that was published again in 2024 beyond our study cutoff date. So similar to that other cost study, this was a 12-month retrospective commercial claims analysis. And again, they looked at, you know, what were the claims for people when they were on CGM, uh, self-monitoring and how did that change when they moved or switched to CGM. What you can find here is that there were significant reductions in this study in all-cause hospitalizations, so a reduction of nearly 19% when compared with self-monitoring. There was a reduction in diabetes related hospitalizations of nearly 50% and a reduction in diabetes related emergency department visits of around 33% when compared with self-monitoring, all of those are statistically significant. And the reductions in HCR healthcare resource utilization measures was significant for all treatment types, so whether that's non-insulin versus basal insulin versus prandial insulin. Again, we've not conducted a formal risk of bias of this, but if you look at this compared with the other high risk of bias study that we have, these are mixed findings. This shows significant reductions with CGM compared with self-monitoring, the other one kind of showed the opposite so, you know, I think this introduces some uncertainty, but again, the caveat for this is We've not done a formal risk of bias, so we're not able to bring that kind of perspective into that judgment.

So in terms of ongoing studies, we identified three ongoing randomized studies. I won't go through these in any great detail, but we've got 23 in adults with type 2 who are not using insulin, we've got one ongoing in children with type 2 who are not using intensive insulin, so that's starting to address one of our evidence gaps, three impregnant people with type 2 who are not on insulin and 10 during pregnancy with gestational, not an insulin, so again, either plugging those gaps or adding to what is a lower level of evidence in some of those populations. A range of CGM types across both intermittently scanned and

real time where we were able to determine that. And then just, you know, some of these studies are pretty small, so 10 people up to what sounds like a much more reasonable sample size of 430. As you've seen before, as with the published studies, most are comparing CGM with standard and 12 are likely to publish in the next year.

Moving on to those clinical practice guidelines. You can see all of the details here, but this is really just a summary. All the details are in your report, you can see pages 60 to 62. So at the time of when we wrote this report, you can see that for adults with type 2, clinical practice guidelines generally recommended the use of CGM for people on insulin, intensive insulin. Also recommended it for people on non-intensive insulin and then as you move kind of into oral medications only fewer clinical practice guidelines are recommending that and then none are recommending it for the use in people who are not using insulin or medications. A similar kind of pattern for children with type 2 with the ADA and NICE, really kind of supporting CGMs for children using insulin and then less so for those other groups using oral medications only or no medication. And then again, a similar pattern you can see here for the use during pregnancy. Intensive insulin or insulin use generally supported the use of CGMs and then a little bit more of variability in people not using insulin or you know, groups saying actually we feel that there's insufficient evidence at this point to make a recommendation, yay or nay, for the use of CGMs. Again, as to note, you'll see that we are citing the ADA standards from 2024. But again, as mentioned today, there has been an update of those ADA standards published in December of 2024, so again beyond our cutoff, but those are standards for 2025 And you can see him in read, here in red, the ADA are now moving into those kind of lower groups about consider offering CGMs for people for adults with type 2 diabetes who are on oral medications only and then for children with type 2 diabetes, again, you know, moving that recommendation down to children, not just using intensive insulin, but who may be on a less intensive insulin regimen. Similarly here, some kind of movement with that 2025 standard using that expert consensus you know, saying that actually, you know, even in the absence of evidence, the expert consensus is saying that there may be some benefit to the use of CGMs during pregnancy. Chris talked very clearly about the payer policies, but I just wanted to say that the coverage policies amongst the public and commercial payers that we looked at generally align with those professional society guidelines. Again, although there's kind of a lot less detail on specific coverage criteria for use of CGM during pregnancy.

So in summary, we wanted to tell you what we know, what we don't know, what is coming and what do other professionals say. So I think what we feel we do know is that CGM use probably results in a statistically significant but maybe not clinically meaningful reduction in HbA1C level when compared with standard testing in adults with type 2 diabetes who are on non-intensive insulin. So it's that small drop really hinges on whether you think 0.5 is clinical meaningful or 0.3. CGM related adverse events, serious adverse events, such as serious hypoglycemia or deaths are relatively rare. And CGM specifically with Freestyle Libre is likely to be cost effective compared with standard daily testing and adults with

type 2 diabetes using non-intensive or that basal insulin and again, that's moderate certainty of evidence with all those caveats about Freestyle Libre only, only that population. What we don't know is really there's no clear or consistent evidence of effectiveness in these other groups, so adults with type 2 diabetes who are using oral medications or in that mixed kind of diabetes regimen population or in pregnant people with gestational diabetes who are not using insulin. And then we've got those three key evidence gaps that we've talked about. We know there's evidence that's in train, 37 ongoing randomized controlled trials of which 12 are likely to publish in the next year, of course, we can't predict if or when they will but, you know, we're hoping that we will start to see some of those and some of those you know, do add to or plug some of the gaps. And in general, clinical practice guidelines commonly recommend CGM for adults and children with type 2 diabetes who are using insulin. But then it's less consistent for those other groups, including during pregnancy. So I think that is the end of our presentation. So happy to take any questions, clarifications, etc.

Evan Oakes

Beth? Could you comment once again on the, I saw the, I don't think the slide about the hospital, that study about the hospitalizations. Can you comment again on that just to make sure I get that? I don't think it's in my version of a pack that I have.

Beth Shaw

This one here with the red writing on?

Evan Oakes

I think that might have been it. Yeah, yeah, yeah. Can you comment on this one again? What is this telling us again?

Beth Shaw

Okay.

Evan Oakes

And why is this is this a more recent one? Is that why you, okay.

Beth Shaw

Yes. Yeah. So this was published in November. Our cutoff date was September.

Evan Oakes

Okay.

Beth Shaw

Of 2024. So we've presented this because it was you know it was mentioned a number of times during public comment and it's been mentioned today you know that CGM reduces hospitalization, it reduces You know, ED visits. And this study does show that it does. However. We've not assessed the risk of bias.

Evan Oakes

Thank you.

Beth Shaw

So, you know, there could be some concerns around the methodology or the methods that they've used. And also, there could be other studies. That have been published since September that have not been highlighted or we've not been alerted to because we've not done those formal searches. So we've presented it because we knew this had been, you know, said, well, why have you not included this?

Evan Oakes

Comment on another thing, a follow-up question, if you don't mind. Do people sometimes ever look, I just haven't really I'm not caught up on it. Do people look at hospitalizations sometimes as a clinical outcome in addition to a cost analysis. I mean, it seems to me that that's a potentially dangerous thing and not impactful to people's quality of life, not just cost but um, can you comment on that a little bit? And do you run into that or encounter that or how is that looked at on the research side?

Beth Shaw

Absolutely. Well, I'm looking at Val and she's nodding. So Val, please, please chip in, but I think you're absolutely right. When you get to some of these outcomes Are they benefits? Are they harms or is

hospitalization a good thing if people are going to their ED sooner you know when the when they're recognizing you know oh I think I might be having some kind of severe hyperglycemic event and I'm no clinician, so apologies if I'm just kind of speculating here, but we often have this question about is hospitalization a good or a bad thing? And I think that's where we bring into our clinical expertise, the knowledge that you all have and that interpretation of the evidence. So Val, I don't know if you want to add to that.

Valerie King

You know, Beth plays a really good doctor on TV. I think it out of the park here. Yeah.

Janna Friedly

And I personally would consider hospitalization a very important outcome. Not just for cost, but for Okay. Laurie?

Laurie Mischley

Yeah, I use continuous glucose monitors in my practice. And I guess my question is, I think of them as a tool like, oh, now I see what happens when I eat oatmeal, now I see what happens when I smoked salmon. And so I don't think of it in terms of the monitor being the therapeutic intervention, but what you do with it. And so I guess my question is about the educational, the package that comes with the monitor and the instructions the recipient receives and so I would expect a really big difference between here's a monitor and here's a tool, let me teach you how to use it. And so can you talk about different studies and how they package education instructions for use with it?

Beth Shaw

Absolutely. And I think, you know, we focused on those clinical outcomes you know we, we didn't look at, you know, do people feel that their knowledge is increased or that they're better able to manage you know, their diabetes, you know, those were outcomes. We'd hope that that would be captured in the quality of life, you know, where I reflected the levels of people's satisfaction with treatment was high and they didn't have high levels of diabetes related distress. What I would say as well though is that some of the studies really did support people, you know, with that CGM, you know, giving them education, giving them lots of support You know, on how to use them you know what to do with the information some of the other studies I either didn't report it, so we're not able to tell or you know, really didn't say what they did. So it's a mixed bag, I would say.

Janna Friedly

I was struck, Beth, with a number of ongoing trials. That's a lot.

Beth Shaw

Mm-hmm.

Janna Friedly

30, 37 trials, I think you said, and with a number of them coming out this next year, I didn't look at the you know what the what those trials are, but is there a sense that that the, the trials that are ongoing are trials that are trials potential, the design of the trials or potential trials that would, could influence a decision one way or the other, like if we make a decision today that these trials come out in a year that we will we might be looking at reversing a decision because of the outcomes of these trials. Are they pivotal trials?

Beth Shaw

There's definitely some of those ongoing studies that are in populations where we don't have any eligible randomized control trials, so there's at least one ongoing randomized control trialing children, for example.

Janna Friedly

Okay. Yeah.

Beth Shaw

Which we don't have. And then some of the others kind of add to this. I mean, I think one of the challenges is, I think I said this earlier, this is kind of rapidly moving, we've got over-the-counter you know devices now and the devices themselves are continually improving you know, I think you talked about this earlier, about, you know, back in the 80s, you were measuring, you know, urine. And, you know, I think we're finding new ways to use these devices about, you know, well, have I just had a milkshake or smoked salmon and I'm learning more about how this impacts me so again, I don't want to influence your toll but it feels to me like this lots of different ways that people are trying to find how to use these and effective as way as possible and maybe simply HbA1C is a, a starting point And so I think

we will learn more. Again, I don't, I'm not going to say anymore because I don't want to influence your decision too much. But yes, we will learn more as these studies come out is the bottom line.

Janna Friedly

Yeah. Other, other questions or comments from the?

Amy Occhino

Oh, this is Amy Occhino. I'm the OB that you guys were referring to and I actually work with Alyson Blum who she works in my office, actually. I didn't know she was going to be part of the discussion today, but she was one of the attendees to discuss the pros of continuous glucose monitors. We use them quite a bit in our high risk OB practice. And one of the studies that you reviewed, Beth, was that between 17 and 33% of people in one of the studies ended up going from being a gestational diabetic not on insulin to a gestational diabetic on insulin and the only way we really get that data in an effective manner to make good outcome and adjustments for that short term that we have during the pregnancy to get things under control tightly, that's where the CGMs come in so handy because we have a week or 10 days worth of data that we download onto a computer and I can make decisions that normally may take me three or four weeks to make because I have a patient who doesn't really follow the diet that I have her on because she's got a birthday party or she doesn't record her sugars or what she's eating for a while. And so sometimes I don't get data for four to six weeks to be able to change my management. So having continuous glucose monitoring for all diabetics in pregnancy, whether they're type 1, gestational, or type 2, to me is hugely relevant hugely necessary. And as you said, there is so much going on with this right now. This is a huge, this is just a large piece of what's changing so much in medicine right now, particularly in pregnancy and so I'm very pro continuous glucose monitoring for anyone who is a diabetic in pregnancy, regardless of what type they are, pre-existing or what have you.

Luke Wander

I think however the committee ends up thinking about this, it's very important to bin the folks with diabetes and pregnancy very separately from these folks with type 2 diabetes on oral glucose lowering medications and things like that. If you look at the, I'm putting on my perinatal epidemiologist hat for a moment. If you look at the impact of hyperglycemia in pregnancy on outcomes in the perinatal period and after birth and in childhood and even in later life in folks who were carried by mothers with hyperglycemia, the impacts of hyperglycemia in pregnancy are graded and substantial and they appear to happen at much lower levels than you would think, even in the normal range of blood sugar, baby's growth is impacted by maternal glycemia. So I think it is very, very important to weigh these groups separately.

Janna Friedly

Val?

Valerie Kin

Yeah, this is really getting at Laurie's question about ongoing studies, but also picks up um on something that Amy just said about the pregnancy population, your, um, the details about ongoing studies are, I'm sorry, on Appendix H in your report and that begins on page 179 toward the end of it. And just if you scan through those many ongoing studies that will report out at some point, the vast majority of them really are among people who are not on insulin. And in the pregnant population, that reflects that they haven't started on insulin, they may at some point but even in children, in adults, there are a lot of the ongoing studies that relate to folks who are on oral medications or on no medications and are not on insulin. In the adult population, there are a few among people who are on non-intensive insulin as an arm of the study, but I think you're moving in this literature base into more and more studies where people are getting less intensive diabetes therapy in terms of insulin or other medications. I hope that helps.

Amy Occhino

I also, oh, sorry. I just want to also point out that we cannot use the oral hypoglycemic medications in pregnancy that you guys all use for your adult patients. We pretty much have insulin and that's it. We do use Metformin once in a while. We used to use Glyburide, but it's been proven to be more risky with really poor absorption and poor management. So we don't have much in our box of tricks for any pregnant diabetic. We have insulin, basically, and maybe Metformin if we have people that have insulin resistance with polycystic ovarian syndrome or some type of metabolic syndrome that had been diagnosed pre-pregnancy.

Valerie King

Yeah, that's true. In the ongoing studies, I think there are one or two where Metformin is part of the comparison group.

Janna Friedly

Great. Thank you. Other questions or comments? Evan?

Evan Oakes

Are we in discussion mode, Janna, or do we have a later discussion too?

Janna Friedly

We'll move into discussion as well, but feel free to ask questions now or ask questions now.

Evan Oakes

Okay. I just, I mean, I wanted to, there's a couple of things that are really on my mind around this one is I'm struck by how different it seems to me that the assessment of this technology compared to surgical interventions or very distinct one-time interventions, how much this feels different than that. And the other thing is the conditions we're talking about, like a chronic condition seems so much different than a single intervention with a specific diagnosis in mind or something and so much of what I'm thinking as I'm listening to this about the continuous glucose monitoring is that And it came up earlier, the whole idea of the access to information and the behavioral components related to chronic disease and how this is not a specific surgical intervention. This is basically a way of collecting information for people. And I'm just struggling with how that aligns with the research because I'm I just don't, I understand like our, you know, I'm trying to be very, you know, honest to our look at the research, that's what needs to drive our decisions and yet I'm struggling with whether or not the whole model or the whole premise of our HTCC right now helps to match assessing whether or not we cover continuous glucose monitors. So those are some of the thoughts I'm having. And I think I have a few others that have come up that I might think of a little later, but anyway, I just thought I'd share that for a moment because that's what I'm worried about. I feel like there's It just feels different is all.

Janna Friedly

And are you suggesting that the study designs are not adequate to adequate answer the right questions related to.

Evan Oakes

Yeah, I did think of that. Oh, sorry. Go ahead.

Janna Friedly

Yeah, that's what you're getting at?

Evan Oakes

Yeah.

Janna Friedly

That the studies are designed to think about this as a as a treatment intervention rather than a And then a tool to gather information as part of?

Evan Oakes

Yeah, I think very much so, because I can't help but to go through my mind of, are these studies picking up the refinement or the minutia that's necessary to make sure that the right people have access to this continuous glucose monitors. I mean, we all sort of manage our diabetes most likely in very, very unique ways. And so how does this continuous glucose monitor assist very specific individuals in that and that's what I worry about. And I mean, I just am thinking out loud for a moment, but the studies tend to assess this at a at a little bit too high of a level maybe is what I'm wondering about.

Janna Friedly

Chris?

Chris Hearne

I'm pretty surprised by the… sort of lackluster benefit in A1C that the evidence report showed. And something I wonder about, and maybe part of what you're getting at, Evan, is that patients manage their diabetes with a wide variety of intensity and interest and techniques and I think in reality, you're not going to offer a CGM to every patient that's on basal insulin. Some of them are going to want it, some of them are going to use that information and apply it and others aren't and that's a decision you're going to work out with the patient when you see them. And so enrolling a bunch of people and then randomizing them to either get it or not get it, I almost wonder if you're including a lot of people who you wouldn't necessarily normally offer this treatment to or think would benefit from it. And so some of the benefits in the patients who do get a lot of benefit are obscured by aggregating it, that's sort of my initial thought.

Janna Friedly

Washington State Health Care Authority

Laurie?

Laurie Mischley

Yeah, if we're moving into discussion, I have some similar thoughts that the data presented here just does not coincide with my clinical experience. And so I don't work with the diabetic population. I work exclusively with people with Parkinson's who are coming to me to have their brain saved as much as they can and elevated hemoglobin A1C is associated with faster brain atrophy, so for the last 20 years, once a year, I measure hemoglobin A1C And there is no question continuous glucose monitors, I've been able to see more benefit in three months than I used to get in three years. I mean, people can decide, oh, look, when I do this, here's what I get, here, when I do this, and now there are online resources. I can put a glucose monitor on somebody and have them go watch Glucose Goddess on Instagram for an hour and they get I, okay, I see the game. What can I eat that doesn't get my sugar spiking? And I just, though, without that tool, I can't imagine how you can make those decisions. In the old days, it used to be like, I don't know if you can eat fruit or not couples will eat it in a banana, a couple will eat a banana, one will spike and one won't and then also in terms of the accuracy of it, I think that that just needs to be addressed. I taught a class on this and I wore a Dexcom on one arm and a Libra on the other and the Libra kept nagging about my nocturnal hypoglycemia while Dexcom alarm went off every time I had a good idea or a couple of raisins on an empty stomach. You know, while they trend together they're not the same and they read differently and the number of calls that start coming into the clinic about nighttime low blood sugar episodes is not insignificant when people start being alarmed to things that they didn't know were happening. So I just do think that as an educational tool, it is a game changer. It empowers people to make decisions that were not possible before it. But I do think having personally worn both competing products for a month, it did shake my confidence a little bit in terms of you know, it changed how I educate patients and how to interpret it and what we do with it. But again, just in terms of what we do with that information, I think that's important just to say.

John Bramhall

I think there's a lot of similarity here with just simple blood pressure monitoring. You know, people buy an automated monitor and it, it, it transforms the way in which they can record, analyze, interpret, follow their blood pressures but it's, it's you know two different monitors are going to give you two different results and In the OR, we look at A-lines and blood pressure cuffs and they may be 20 30 millimeters out and you just have to make some kind of judgment and I suspect that probably the, the fine line through is to be consistent in the modality that's used and, and take the trends that come from a single determinant or a single methodology. I mean, a single manufacturer even. I just think there's a lot of parallels here with hypertension monitoring.

Janna Friedly

Yeah, but I think that the evidence question is whether that kind of intensive monitoring changes outcomes and really changes outcomes and there's been in history times where we have realized that intensive monitoring of various kinds that we think that more data helps us and it doesn't necessarily improve outcomes in the ways that we think it does. And I'm sure there's some examples, and I'm sure I'm going to butcher some, but I think with fetal monitoring, there's been some ups and downs in the evidence of that or arterial line monitoring or other examples where that there's some controversy about whether that kind of monitoring. So I think from an evidence standpoint, that's what we have to we have to go back to whether or not that that monitoring um does in fact change outcomes. And I do think you can answer those questions with research studies. Dr. Chen?

Christopher Chen

Yeah. Thanks, Janna. Yeah, is it okay if I just talk a little bit about our recommendation and comment on some of the discussion so far.

Janna Friedly

Yeah.

Christopher Chen

Yeah, I just want to clarify you know, I think just based on the discussion, there's a lot of debate about whether CGMs are valuable or like in what ways they are. I just want to give context. Our recommendation is not saying that CGMs aren't useful, I think they've clearly kind of demonstrated value in many different patients and I think just wanted to frame it because in a resource constrained environment, especially in the setting that we find ourselves as a state. We are always kind of pushed to ask for whom is the given technology most beneficial? And they're not cheap devices. They can be $2,000 per client per year which the manufacturers do charge insurers more than they can be available in the over-the-counter market and so I think there's some interesting pricing dynamics going on there. And so given in a world, if we had unlimited resources, I think there, you know, we'd be having different discussions, but in a resource constrained environment like where can we think about like for whom these interventions are the most effective and I think that during the public comment, we heard lots of testimony about, you know, for this patient, there was like 2% or 3% reduction in A1C. And I think randomized control trials are still the best way to evaluate the effectiveness of different technologies and we have seen a number of those today and I would not be surprised if they're different confounders in real life clinical practice I think as we've heard allusions to other technologies like a Fitbit, if someone could make a claim, I give someone a Fitbit and it makes them healthier. Well, people who get Fitbits are

also much more motivated, they're much more likely to be on a trajectory where they want to improve their health and so I think There's potential confounders and, you know, when we look at the evidence, there just weren't really significant, at least not as significant as the claims that have been made in terms of reductions in A1C, at least for the type 1, type 2 diabetic population, I know that there were discussions about other relevant metrics. And I think to your point, there is still this question about how much data is enough data. I don't necessarily need a CGM to know that eating a tub of ice cream and a pack of gummy bears is going to make blood, blood pressure go high. I think, you know, CGM will confirm that. And so I think it's, again, they're valuable technology the question is just for whom and what is the evidence telling us about that?

Janna Friedly

Great. Thank you. Laurie?

Laurie Mischley

Yeah, and just a, does this have to be all or nothing? I mean, I feel pretty strongly about this being an educational tool that I would like to not restrict access to for at least some people for a short period of time. We're talking about $2,000 per year, but in my practice, I have people wear it for a month. They see what oatmeal does, they see what it does, they learn a couple things, they go on. They don't wear one indefinitely. In our coverage decision, even though it wasn't how the evidence report included it, could we consider something like, you know, one to three months per year for a group, just as an educational tool would be my question.

Janna Friedly

Yeah, that's a good question. None of the studies were framed in that way and the patient population, you know, obviously pregnancy is a time limited, so that's going to be a time limited use, but for diabetes is not a time-limited you know, can necessarily condition. And so I think, I suppose you could, you could consider any kind of condition that we would want to write but that none of the studies were designed in that way, so it wouldn't be an evidence-based condition so I don't have a good other answer to it other than that.

Laurie Mischley

No, I was thinking just in terms of a resource constrained environment, that might be a good way to provide people access to that tool with being respectful to resources.

Janna Friedly

Yeah, it's an interesting idea. I don't have any other around that? Evan?

Evan Oakes

I don't have anything. Oh, finish that thought. I don't.

Janna Friedly

I don't know, does anybody have any other thoughts along to Laurie's point before we. Yeah. Val, were you going to address Laurie's or move on.

Valerie King

Laurie's. You'd have to look really carefully at what your sunk costs for devices are. Because the ongoing costs of CGMs are really related to the additional supplies that you need, not the monitor itself. And so you may have the big one-time cost of the continuous glucose monitoring no matter what, if you were to do a small amount of time coverage. You'd have less supplies that were ongoing through the year, but you'd still have the major expense of the monitoring.

Janna Friedly

Yeah.

Valerie King

There are these sort of disposable monitors now, you know, some that the over-the-counter one is in that vein where it's so, you know, what I'm saying is only applicable to things that have a monitor that is not disposable.

Janna Friedly

Laurie, it sounds like you have some research studies to do. Evan?

Evan Oakes

Well, I just wanted to reflect a little bit on the comment Christopher made about the costs. I appreciate that always. I mean, that is certainly what we are sitting in and I also totally appreciate that we need to make the decision today on kind of the evidence that we have. But boy, if we find that this reduces hospitalizations, that could pretty quickly cover costs of CGMs and so I just, I think there's longer term considerations around costs that I would want to make sure we were not missing out on. So I guess I'm wondering if there's a way for us to come back to this topic in a relatively short term when some of those research articles might be more available because I just really, anyway, I just really think that it's something that I mean, it's not just a matter of more information may not mean anything. I think it's, again, it's for some people, it means a lot, I think. And I'm trying to, I just, I'm worried that we missed something about that so that's all.

Janna Friedly

Yeah, and there is, you know, definitely a process for rereview with new evidence. This, that's why I was struck as well with the number of ongoing studies and even since the report there's studies that have come out that have already been published. So it definitely feels like it's a, it's a moving target. So it feels like even with a decision today that this is a topic that we will need to that should be looked at, at least carefully for carefully signals for rereview. Any other comments? We've sort of bled into discussion and um question and answer for evidence. I think we have, we have, we are way off of our timed agenda. I think what we, the next part of what we need to do is to do our straw poll votes and get into our decisions and if we are moving towards cover with conditions um our language. I suggest that we take a very short maybe, uh, break until 2:15 until just think of us a short break before we get started with that, that's okay with everyone? Okay, so let's reconvene at 2:15 for that.

Just give people a moment to Get back on. Thanks for taking a short break. It's been a while since we've done two topics in a day.

Josh Morse

It has.

Janna Friedly

We used to do them frequently. Okay, I think we have most people. Don’t see, Jonathan. But Josh, while we're waiting for last committee member, there we go, we can, we're going to get started with straw poll at this point so I don't know if you want to pop up the.

Josh Morse

Yeah, I think Val will be doing that.

Janna Friedly

Slides again.

Melanie Golob

And, did you want to talk about the sufficiency of evidence or move right into this straw poll?

Janna Friedly

I think we can um I think we have, unless anyone has any other comments About the evidence, I think we can move into the straw poll.

Val Hamann

That sounds good. And how we did this is CGM as a whole for safety and cost and then for efficacy, we did break that out between non-intensive and pregnancy. Did you want that differently or does that sound okay?

Janna Friedly

I think that sounds okay. Yeah.

Josh Morse

Okay, I just want to point out we're skipping over the conversation about outcomes. I think, right? We haven't gone through. Yeah, slides 8 through 11 are just about, yeah, I think this is important to go through here to make sure that before we get to the vote.

Melanie Golob

Okay. Are there other safety outcomes that should be considered other than these that were available in the studies?

Janna Friedly

Well, I think these are, I guess it depends on what you consider safety. So these are safety outcomes that are related to the device itself. If there are safety, if you're thinking about safety outcomes in terms of prevention of hypoglycemia or hospitalization or um, you know those I which are outcomes I think those are also kind of safety, so I think it just depends on how you categorize those, but they might say it doesn't matter.

Luke Wander

For a lot, but not all of these groups studied, the risk of hypoglycemia is quite low, right? We're not giving them anything that would make their blood sugar low and there's nothing to titrate that would do it, so it only counts in the insulin folks, I think, and folks who would be in treated with orals that would cause hypoglycemia like sulfonylureas.

Janna Friedly

Or yeah, if they didn't have a glucose, I was thinking if they didn't have the glucose monitor that they would that you might miss hypoglycemia. Yeah.

Luke Wander

It shouldn't be happening, though, in these populations. They're a little different than the T1D population or the T2D population.

Janna Friedly

Yes, that's a good point. Yeah, got it. Makes sense. Evan?

Evan Oakes

Wondering about the machine accuracy and how that might relate to this or not. It might not, I just was like you could get, you know, sort of, I can't remember what the study said is why I'm bringing it up so if somebody please just speak up, but you could get hypoglycemia if the machine read that you were

normal and you didn't pick that up. I didn't know how if that, you know, in other words, inaccurate reads. So that may not be applicable. Dr. Wander, I find I just was wondering about that.

Luke Wander

Yeah, it's a nice question. And I think in these populations, it's less, it's less important than in folks who you're sort of, you're using it to titrate inputs, right? You're using it to titrate your insulin input because here, you don't expect like this is a person, if you think about if you visualize them clinically, it's like a woman who is on metformin or something, right? And so metformin won't cause her blood sugar to be low. And so a miscalibrated system, the, the bad outcome would be that it would see a low when a low wasn't there, but in the person's body, that wouldn't biologically be happening. And what the teaching, the way that the sort of start people out is they talk more about trend and less about individual numbers. So often the Dexcom G7, for example, is one that has historically had some more issues with calibration than the G6 system and so people will often know, they'll check a finger stick measure to see how different it is, but you can still follow the trend. So you can see it's going down when I walk or it's going up when I eat.

Janna Friedly

Any other safety outcomes we're missing? Okay, I think we can move to the next slide. And then, and then efficacy, you know, and this is efficacy for efficacy all populations or this is efficacy or this includes pregnancy?

Melanie Golob

No, we separate that out for special populations.

Janna Friedly

That was. Okay.

Melanie Golob

Yeah. And these outcomes, the HbA1C that that's not just you know change in HbA1C but I think some studies had target HbA1C and then the different quality of life. There are a lot of different quality of life scores.

Janna Friedly

Okay.

Melanie Golob

So are there any ones missing from this efficacy list?

Janna Friedly

Jonathan?

Jonathan Staloff

I didn't really see them in the studies presented but um I would say Hb1C for diabetes is an intermediate outcome rather than the outcome we're most interested in. And so for diabetes management, A1C control is sort of a sort of vehicle for trying to prevent the more clinically meaningful outcomes like incidence of diabetic kidney disease, diabetic retinopathy, ASCVD risk, I don't think necessarily that the studies reported on that, but I would say to the extent that this is a technology that achieves greater diabetes control, I think those longer term end organ damage outcomes are relevant, so I'd say diabetic kidney disease incidence and severity, incidence of vascular disease.

Janna Friedly

You probably could just say and organ damage or diabetic complications.

Jonathan Staloff

Perfect.

Luke Wander

Complications, yeah.

Janna Friedly

To capture all of those. Great. Any other? Okay, perfect. Great. Yep, go ahead.

Evan Oakes

Isn’t it, isn't glycemic variability a factor? I thought that was becoming more important in the management and whether or not we, I didn't know if this list was supposed to be what was covered in the studies or if it was supposed to be what we consider possible outcomes. That's why I brought it up.

Melanie Golob

Yeah, and I think it's kind of both. So the ones that we show are the ones that were presented in the studies but kind of what this discussion is supposed to do is more to get you think about are there other outcomes that would have been helpful in making your decisions that aren't presented in the studies? Like maybe they haven't been researched yet or you know they're not in the studies for whatever reason.

Evan Oakes

That's helpful. And in that case, then we had, I did bring it up earlier and we had kind of talked about hospitalizations themselves as outcomes. I don't know that ER visits are that or not, but hospitalizations kind of feel more like that maybe than others. Just a thought.

Janna Friedly

Jonathan, did you have your hand up for another.

Jonathan Staloff

Yes, especially if we're thinking about costs and um the cost of some newer agents like GLP-1s. I think one outcome that was not present, but could be worthwhile to know. is if um, if there's any sort of data around prevention of needing additional, additional antihyperglycemic agents. Like if someone's on metformin alone and this keeps them on metformin alone rather than progressing to needing a GLP-1 and an SGLT2, etcetera, etcetera.

Janna Friedly

So I don't know how to word that prevention of escalation of treatment need or something.

Jonathan Staloff

Washington State Health Care Authority

Love that.

Evan Oakes

Or polypharmacy?

Val Hamann

Would you like polypharmacy? Or.

Evan Oakes

I was just throwing that. That's sort of what we're talking about. But that may not catch what you're trying to say, Jonathan, but I was thinking that that may be the term that is what we're trying to avoid more medications.

Jonathan Staloff

Yeah, I guess prevention of medicine escalation or prevention of poly, or future polypharmacy.

Luke Wander

To take a devil's advocate position on that one or for consideration of the committee, usually those addition of glucose lowering medications is largely driven by A1C. That's the sort of still in type 2 diabetes, the metric that they use to decide to escalate so does that add much over just looking at A1C metrics?

Jonathan Staloff

I guess the one thing, and maybe the studies capture this in their inclusion criteria, right? But maybe, you know, as an interval outcome someone could have an A1C of 6.5 in the study on metformin and Ozempic, or they could be have an A1C of 6.5 on metformin and a GLP-1 and the study would stay for both people that they have an A1C of 6.5.

Janna Friedly

That's a good point. Okay. Any other outcomes? Okay, let's go on to the next and then cost and cost effectiveness, I think that's straightforward and then, yeah, special populations. Yeah, so with pregnancy, I think we spent quite a bit of time talking about perinatal outcomes, which I think is important in addition to the hemoglobin A1C. Yeah, Evan.

Evan Oakes

You know, I didn't speak up to the last topic, but we don't have other demographic I'm sorry, this is supposed to be like demographic outcomes, right? Like we don't have something to reflect different cultures or different cultures things like that. I don't know if it's relevant, ethnicities what is it you know what how does these different things impact different groups of people that have different cultural beliefs, stuff like that. We don't really capture that in these lists and I wondered if that was relevant.

Janna Friedly

Yeah, I think this is really intended to capture any populations of patients that may be different, that maybe have different outcomes or different responses to the treatments that we should consider, particularly in thinking about the evidence and special considerations for coverage or covered conditions for coverage or things like that that need to be called out. There are oftentimes when we do this, there may be important differences, but not, not enough evidence to guide us in that. So there may be differences in ethnicity of things that are just not captured in the studies. I didn't hear, it didn't sound like there were any subpopulations, at least in the evidence report that were that were called out in particular. Doesn't mean that they're not important.

Evan Oakes

No. Sorry, just for clarification, Janna, when you say that, you mean that this list is supposed to be those that we actually saw in the research stuff we studied, or this is supposed to be considerations we want to be thinking about?

Janna Friedly

Both.

Evan Oakes

Yeah, okay.

Janna Friedly

So inclusive of both, yes.

Evan Oakes

Because the other. Yeah, so we probably should have something on here then about either ethnicity or cultural ethnicity background. And then the other one I just want to capture that we haven't talked a lot about social drivers. You know, certain populations might have very specific social drivers that are impacting their well-being or their ability to do medications. How do those captured in research and stuff like that?

Janna Friedly

John?

John Bramhall

We sort of glossed over the cost slide before. I'm not sure whether this is, you know where we would have a discussion. There's a little bit of information in the report that gives us some clues. about cost effectiveness there's the report that was a little bit, you know, it's fast moving that 2024 paper that was brought to my attention by Garg. And that kind of report seems to just more than suggest, I mean, one of the authors of that Garg study is uh, very eminent very eminent well-versed researcher in clinical management of diabetes and the molecular mechanisms. It's not a trivial paper, the authors are outstanding. And, you know, a paper like that I'm not quite sure what we do with it. It seems to me that diabetes is a huge, huge cost, financial cost and suffering cost in the nation. It's getting worse. There's a variety of ways in which we attempt to manage diabetes, treat it, cure it. This tool seems to me the continuous glucose monitoring just seems to me that this is the way we should be monitoring glucose now forget the urine you know in the 80s. This is what we should be using um, this is it. And there's an incremental cost I looked up the cost of the devices. They're all over the map, but the devices are not expensive, 150 bucks or something it's nothing It's the cost of a blood test, right, in a lab? And there is a cost to chem stakes that people presumably are using as an alternative to this. If any population that we're looking at is being managed for diabetes and it's being managed in a way that requires monitoring of glucose at any reasonable periodicity, it just seems like well, there's so much advantage to this technology and it's going to cost, okay, maybe it costs $500 a year more or $1,000 a year more than the chem sticks something like that, these are not big costs for the major disease that that we're facing. And so anything, almost anything that helps us manage diabetes, reduce the comorbidities is going to be

beneficial. It's really hard for some of these studies to look at retinol issues and look at amputation rates 30 years after the onset of diabetes, it's really hard for these studies to capture that, I mean all you can do is look at what you're faced with on a daily basis is people having the feet cut off, people going blind, people overweight, just simply overweight and not managing the disease very well. And here's a technology that gives you a readout, it gives you something you can plot, you can translate it to your cell phone, you can take it to your clinician's office and show the trends up and down at night, that's information that you're not going to get any other way and honestly, I think I'm very, very much persuaded by the data we're presented today and also very much persuaded by just the common knowledge that we all have about the about the role of diabetes in in morbidity in our country that this is a technology that we should be not restricting on the basis of very almost trivial economics like we don't have any money. I get it. We're going to have way less money in a few months time. We're going to have to deal with it. We're going to have, you know, $880 billion less in Medicaid. That's not the reason to just give up and not manage in the way that these cases should be managed, in the way that they can be managed. What I'm sort of getting at is that I don't think that we, we can sort of argue them along the lines of, well, what does diabetes do to you and, and, you know, are we going to be able to prevent everything the diabetes ultimately causes in a variety of populations. No, I'm simply arguing that the if the disease is being managed now by clinicians, the clinicians ought to have available to them the technology that seems to be best suited to management of, of diabetic illnesses and this technology seems to me to be better than chem sticks better than probably be better than A1C in terms of variability and better than urine tests from the 80s. That's sort of where I'm where I'm at and that's probably going to guide my voting.

Janna Friedly

And Dr. Chen, you had your hand up. And then I saw it go away. Did you, did you have something that you wanted to?

Christopher Chen

Oh, thanks, Janna. No, I just want to, just to add context, I think we did give a range about $1,000 to $2,000 per client per year on the commercial side, that is about $2,000 per year. I think, I mean, I think everyone in this room probably knows that healthcare is not a perfectly functioning market. There are many reasons why that's the case. There are three main manufacturers in this space and that all have their own kind of pricing dynamics and profit margins. And so, you know hypothesized ways of managing pricing, like competition don't always pan out more broadly speaking. And just recognizing Dr. Bramhall's considerations have brought the broader fiscal environment, both in the state and the federal level, I think underscore some of those previous comments around the resource constraints that we operate in any time it comes to cost, so yeah, I mean, if this costs $200 a year, I think the conversation would be very different, but if we have, you know, even if it was five to, you know, we have 2 million people on

Medicaid, probably I think around 6% of our patients are diabetics, if we were to theoretically were to increase by five to 10,000 clients a year that would amount theoretically at a cost of $1,000 a year to five to $10 million additional Unfortunately, I don't actually have actual modeling for the committee, I wish I did in terms of our own more robust claims analysis in terms of understanding cost effectiveness as well as potential modeling, but especially during session, unfortunately, our modeling capabilities and our resources are not enough to support more kind of robust data analyses to that end.

John Bramhall

But thanks, Dr. Chen. And I'm not being naive. I appreciate the constraints that the HCA works under. I mean, I really do. But there must be a cost there's a cost to, a cost glucose monitoring that exists now, so there's a population of patients

Christopher Chen

Yes, I think, yeah, no, I agree. And theoretically, as someone goes on CGM, they're self-monitor blood glucose costs also theoretically go down, especially with test strips, which we know kind of providers indiscriminately prescribe 100 a month for all the time. But what I did also hear was that people still do use self-monitored blood glucose monitors, also either to calibrate the CGMs or to intermittently check it when their CGM function isn't, so I think there's, it's not a zero cost that it goes to at least.

John Bramhall

All right.

Christopher Chen

Yeah, and I agree. I think there are hypothetical cost savings as well. Again, I just unfortunately don't have our own analysis to understand that or didn't understand anything harder than a simulation in the simulation Although there was that one study, although the numbers kind of felt a little bit too good to be true, but I honestly, I would have to look into the study a little bit more to be able to comment on that.

Janna Friedly

Great, thank you.

Luke Wander

Another nuance to that as you're thinking it through finger stick glucose isn't recommended for all populations, regular finger stick glucose isn't recommended for all populations with type 2 diabetes, if they're not on intensive therapies.

Janna Friedly

Okay. Great. Let's go on to the next. Okay, so I think now we're on to the sufficiency of the evidence and our straw poll votes. So I think we need to, Val, pull up our ttpoll again.

Val Hamann

Yes, I was just getting that started again. So that is now up and when I see eight connections, I will launch this first poll. I'm just waiting on one more connection. We have eight. And that first poll is open. And then we'll move on to efficacy. And again, you will have two votes. One will be on non-intensive and then we'll do the pregnancy. Okay.

Janna Friedly

Okay.

Val Hamann

And then again, this will be the pregnancy. Then we will move onto cost.

Janna Friedly

We're all over the place there. And that was the last one, right?

Val Hamann

Yes. Is there any you would like to go back and look at?

Janna Friedly

Okay. I think to me it looks like there was like there was fairly consistent in terms of efficacy for both low, low, low confidence, more, more, um, efficacy with the treatment with low confidence. But less agreement about data related to cost and cost effectiveness for, for the monitors. So I think, I don't think we need much discussion there. Let's go to the next slide with the decision tree. So I think at this point. I think we have based on what we see in the straw poll, it looks like we're leaning towards yes for sufficient evidence for safe, safety, efficacy, and cost effectiveness or at least safety and efficacy. So it's taking us down the yes, but then u, we'll need a straw poll vote for coverage.

Val Hamann

Okay, and you're ready for the straw poll?

Janna Friedly

I think we should do the straw poll and see where we're at.

Christopher Chen

And sorry, Janna, can I just remind the?

Janna Friedly

Yeah.

Christopher Chen

So there's just the scope of the decisions. Okay. It's also in the poll itself, the scope of the decision was for non-intensive insulin for type 2 diabetics and then the specific populations for pregnant. Thank you for incorporating that into the slides.

Janna Friedly

No. Yeah, they're broken. They're broken out.

Val Hamann

Okay, so it looks like six for covered with conditions and two for covered unconditionally. We have three for covered with conditions and five covered unconditionally.

Janna Friedly

Yeah, and actually I made a mistake on mine um so.

Val Hamann

Would you like me to relaunch?

Janna Friedly

Well, I don't think we need to relaunch, but I meant to put cover unconditionally because I don't, I don't know what the conditions would be that I would restrict. For pregnant people with um, in this category with type 2 gestational diabetes not using insulin. It should be six and two. Are there Do we want to have a discussion about either of those two, are there any other, anyone from the group want to have any comments about either of those two? It looks like if there's no discussion specifically, then it looks like it's a cover unconditionally for pregnancy and cover with conditions and then we moved to move coming up with the criteria for coverage for adults and children. Does that sound reasonable? Okay. Do you want to pull up the draft language from the agency?

Josh Morse

Yes, I have that up. Let me just clear my toolbar here. So this is the languages proposed by Chris, Dr. Chen. And this is the complete language, this includes elements we may need to practice isolating some of this because your decision is related to your decision is related components of this and then there's some modification of existing language that's proposed, so if that's not confusing, let me know.

Janna Friedly

That is definitely confusing.

Josh Morse

Yeah.

Janna Friedly

So I just want to make sure I understand what's in scope for what we what we need to.

Josh Morse

Chris, do you wanna, you came on camera.

Christopher Chen

I'm not sure what I. Well, I guess I can make suggestions for the language if according to your guy's decision um but yeah, I don't want to get in the way of the conversation at all. I feel, I think it might be helpful to work out the conditions for the type two diabetics not on intensive insulin therapy and then revisit the individuals on intensive insulin therapy after you kind of lineup on the scope of the conversation today.

Josh Morse

That's helpful.

Christopher Chen

It's just the fragmentation because it is very confusing.

Josh Morse

So this, okay. Yeah. So I'm going to. Let's just start a fresh page here. Does that make sense, Janna?

Janna Friedly

Yes, I think so.

Josh Morse

Because the existing language is type 2 diabetes using intensive insulin therapy and these are the three criteria for that population. I could copy and paste this and we could say non-intensive insulin therapy and work from there or we could start fresh.

Christopher Chen

And I'm sorry, you know, before we do that you, um, I'm wondering also if it's helpful to break down the category of the type 2 diabetics, unless you already had another poll set up, Val, for those who are on insulin and those who are on just orals.

Val Hamann

I definitely can set that up.

Christopher Chen

I don't know. Yeah, Janna, if that's your decision.

Tony Yen

Hey, Janna?

Janna Friedly

Yes, Tony.

Tony Yen

What do you think about just changing on the first bullet individuals with type 2 diabetes who are on insulin therapy.

Janna Friedly

Yeah.

Tony Yen

So instead of because then they'll cover both intensive and non-intensive. Frankly, those are the conditions that I would actually ask for,

Janna Friedly

And just that that covers, does that cover everything?

Evan Oakes

Pregnancy. Jumping down, that needs to be addressed. I think. I don't think we were thinking it would require insulin therapy in that. Is that correct, everybody?

Janna Fridley

So that would just deleting the and require insulin therapy?

Evan Oakes

I think so.

Christopher Chen

Yeah, so that would address the components of the, sorry, again, the way I structured it was the existing decision was on top, the new decision was on the bottom so we're basically addressing all the pieces of the bottom and trying to incorporate them into the top. So that addresses that bullet point that Josh mentioned, that Josh crossed out. So if you get rid of that, if you cross out that whole thing, because then we take care of the pregnant population and then we also take care of non-intensive insulin regimens and then the only thing left to clarify then is whether CGM is an uncovered benefit for those who are not on insulin therapy.

Tony Yen

Chris, do you think it would be helpful to put the little parentheses over there right where the cursor is except for pregnant individuals?

Christopher Chen

I'm sorry, what was that? Oh, I see. Oh, uh-huh.

Tony Yen

Exactly. I think with what Val or Melanie's doing right now, do you think that'd be helpful?

Christopher Chen

Yeah. Yeah.

Tony Yen

Okay. It's the fastest edit I've seen so far.

Janna Friedly

Mm-hmm. Yeah. So I guess the question is do we need to take a separate, do we need to do a separate vote for the type 2 diabetes not on insulin therapy or do we, do we just, can you incorporate it into this decision? Sounds like you want us to do it as a separate decision is that what I'm hearing, Dr. Chen?

Christopher Chen

Oh, Josh, what do you think I don't know, because there was a vote uncovered with conditions. I don't know if the insulin therapy or non-insulin therapy technique would count as a condition or you want that structured as a separate vote?

Josh Morse

Yeah, let me just look at the, um, our team kind of talked about this yesterday. And Val or Melanie jump in here but we looked at the included populations, right? So I'm going to share, I'm just going to share my thought process with you by looking at this document. This is the key questions document. So adults with type 2 who are not on intensive insulin treatment, children who are not on intensive insulin treatment, pregnant people who are not using insulin and pregnant people gestational diabetes.

Christopher Chen

Okay.

Josh Morse

So I think we're okay without doing that separate vote. You're crafting you're crafting criteria that kind of splits this population that's not on insulin, intensive insulin treatment. Does that make sense?

Christopher Chen

Yeah, and yep.

Josh Morse

Okay.

Christopher Chen

Yeah, and I don't know, maybe it's more information than you need, Janna. In some sense, you almost don't need that bottom the non-covered because you have what's covered up top, right? You don't necessarily need to have a non-covered for everything that's covered and some of this is a little artificial because I highlighted the bottom just to try and make it clear what the committee was voting on.

Janna Friedly

Oh, I see. Because you're only covering it if you're on insulin.

Christopher Chen

Yeah. Exactly, right. Exactly.

Janna Friedly

Therapy so you don't need to specifically say that you're not covering it, yeah.

Christopher Chen

Yeah, so I put that down there just to highlight what you guys were voting on. But if you guys don't feel like you need that non-covered statement at all, then. Yeah.

Janna Friedly

Yeah, yes, you're right. It's redundant. I mean, yeah, it's redundant. You don't need to have that at all. Okay. Does that? How does that look to everybody?

Laurie Mischley

I guess I'm confused. Didn't we just say that we had a low confidence that it was more effective in people not on insulin? Isn't that how we just voted in the straw poll that, that. In the straw poll, are we saying we don't want to provide any coverage to people not on insulin? That wasn't the impression I got, but maybe I heard it wrong.

Josh Morse

Val, do you want to go back to those slides? Janna, if that's what you guys want to look at? I think it's phrased not on intensive insulin therapy from the key questions, but I could be wrong.

Laurie Mischley

I feel like in a strong poll, we just overwhelmingly said we had a little bit of confidence it was more effective and then when we went to the conditions, we were like, yep, no. Am I reading that right?

Janna Friedly

So is there sufficient evidence that continuous glucose monitors have a meaningful impact. on adults and children with type 2 diabetes, not on intensive insulin treatment. So, and we said, oh, I see. And so you're saying, and so we said here more, more, so yes, we think that there is evidence, but low confidence that it's more effective on people with on not intensive insulin treatment and you're suggesting that this this includes oral medications in this, is that what you're saying, Laurie?

Laurie Mischley

That was how I was voting is that I thought there was a little bit of confidence that that was my intention when I voted, that may have not been what the slide was asking or meant, but I was saying that I thought there was a little bit of confidence that even in people not on insulin, there might be some benefit. I don't know if that's how the team was voting, but that was how I took the question.

Janna Friedly

Okay, so it sounds like then we do, we probably do need to clarify that. Evan?

Evan Oakes

That's what I was going to say. I read it a little different. I read it as the specifically to the intensive insulin treatment, so I think it's a good point. I don't think we did a vote here on oral meds only, non-intensive insulin, that kind of thing. I don't think we distinguish that, but that, so I think it's a good point.

Janna Friedly

Okay. So it sounds like, sorry, go ahead.

John Bramhall

And my. So my personal vote was, yes, it was the same issue of intensive versus non-intensive. So I thought that any insulin use was encompassing this question.

Janna Friedly

Okay. So it sounds like we need to take a step back and, uh, ask this question again but um specifically with oral medications in order to see where people are.

Jonathan Staloff

One clarifying thing.

Janna Friedly

Not on insulin.

Jonathan Staloff

Due to the. Yeah, because of injectables.

Janna Friedly

Sorry, not on insulin.

Val Hamann

Is that how you would want it?

Janna Friedly

Yeah.

Jonathan Staloff

If the question was to me as well, yes.

Val Hamann

Would you like to vote on this?

Janna Friedly

I think we should vote on this, yeah.

Val Hamann

Okay.

Christopher Chen

Sorry, Val, I think we should also keep the vote. From the last.

Val Hamann

Yeah, we have this. Yep.

Christopher Chen

Okay. Okay. Okay, perfect.

Val Hamann

And that poll is open. We're waiting on one more. There it is.

Janna Friedly

Okay. So, definitely more split, but equivalent of the majority equivalent. So I think, can we take a straw poll on coverage then for that question?

Val Hamann

And again, you just want it on insulin?

Janna Friedly

Just… Not on insulin.

Val Hamann

Yeah. Yep.

Janna Friedly

Okay. We have an even a number of people. So we have four non-covered three covered with conditions and one covered unconditionally. So I think we need a little bit more discussion about this. Chris?

Chris Hearne

Oh, I'm just, I, I voted not covered. But if we're thinking of conditions that this would make sense in it perhaps it would be for patients with type 2 diabetes who are on like a sulfonylurea and are having hypoglycemia, that might be a reasonable condition.

Laurie Mischley

You know, I'll just speak up one more time about disparities. I really see that the patients who are in a position to go buy their own are getting different outcomes than patients who aren't. And so we have this interesting situation where there is what is covered through the traditional channels, but you can also get an over-the-counter one. It's just striking to me people who struggle with trying to get their blood sugar down who can spend the $80 for a Stella or who can't. And so my push to cover with conditions is in the spirit of education and prevention and lifestyle management and getting control of your own blood sugar and preventing more expensive, devastating long-term outcomes and trying to get something a little more equitable across the population is that becomes more and more problematic. And just in terms of being respectful of costs, if the decision is not cover, cover, if there's any wiggle room in anybody's opinion, I'd just like to again reintroduce this idea of maybe even a month or two or three per year just to get somebody a little bit of education and opportunity and tool to see what happens with a bowl of oatmeal in the morning, bowl of cereal versus protein. So, anyway, it's the disparities that are really pushing me to say cover with conditions to get access to the people who have not had access.

Josh Morse

There's a hand up, Janna.

Janna Friedly

Oh, sorry. I'm looking at the, the tables. Jonathan?

Jonathan Staloff

Echo much of what Laurie said. I also voted to cover with conditions with a similar framework of, I would say, limited use for this population and for the on insulin but not intensive insulin regimen. I think the question that I struggled with all day and I actually didn't really know how I was going to vote until the very end, but much of the conversation swayed me. I think the question I needed to answer for myself is

do CGMs have, can CGMs have value in insulin management, I mean, in diabetes management beyond insulin titration. And once I landed on, yes, I think they can contribute value to diabetes management beyond insulin titration, I figured lumping, there was no differentiator for me for on a non-intensive insulin, but on insulin versus not on insulin at all. And so I put covered without conditions for both because for me, the differentiator was not intensity of insulin, but rather, is there any value outside of insulin titration?

John Bramhall

To me, the intensity of glucose monitoring is also a factor. I'm ignorant on the management of adults and children with type 2 not on insulin and not one informed, you know if they're taking blood sticks four times a day and that's a meaningful part of the way in which the disease is being managed that I, I would, you can sense from what I said before. I would say do it the better way, but if they're blood sugar measured once a week, then it makes a big difference. No, you don't want continuous then. Those of you that have clinical experience with this type of population, which of those two extremes is likely to be the, the right way to look at it, adults with type 2, they're on metformin or something, they're not going to get hypoglycemic but How often are they going to be measuring their blood sugars?

Luke Wander

The ADA's guidance on this says that what is recommended is that you don't check them routinely, you do if somebody's like, you know, ill or if you're adjusting medication doses.

John Bramhall

Okay, that sort of answers it for me a little bit then. So it's not an intensive monitoring regime in any way. All right. Thank you. It's really useful to me.

Janna Friedly

And for me, I am just going back to the, the evidence there's just the evidence there's, the evidence does not show that there's a difference, um, a change in hemoglobin A1C with this population. So I, I've not covered and I, you know in thinking about thinking trying to be responsible use of the resources that we have, you know, and sort of thinking about the right population of patients to use this for I do, that's how I'm approaching it and how I came to a not covered for this particular population.

Tony Yen

I also voted to not cover because, Janna, like you said the evidence doesn't support it, at least in my interpretation of the evidence. Also kind of like looking kind of at the greater society guidelines I don't know if CGMs are commonly used for people who are just on oral medications or, or on non-insulin injectables? I don't know. And Dr. Wander, you probably know about this stuff way more than I do. If we recommend CGMs now for people who are taking say semaglutide or other injectables.

Luke Wander

So I think Dr. Ehrhardt showed this slide. The ADA's guidance just this year was broadened. I don't want to tell you something wrong that was in it. I'm looking.

Valerie King

It's back at the end of Beth's slides.

Luke Wander

Oh, yeah. Let's look there because I don't want to tell you something that's not congruent with what she said.

Josh Morse

Thanks, Val.

Tony Yen

And also to give you my kind of take on this whole thing I think the society guidelines are probably the most generous out of them all. And that's probably the broadest possible recommendation that can be given. It was curious to me that the society recommends a lot of this sort of stuff and yet the evidence doesn't necessarily support some of the society guidelines recommendations, at least in my interpretation.

Janna Friedly

Evan?

Evan Oakes

Yeah, Tony, thank you. I'm the one over there on the covered unconditionally, but I was right with everybody, right on the, you know, I'm kind of in that same ballpark and I get it that the evidence might not be there, so I could flip pretty easily and then our problems would be solved, I guess, from a majority standpoint. And I think to your point, Tony, I think that was, wasn't that a slide that was shown also by, sorry, I think it was Beth. it's not included in our packet but there's again, this is what I had kind of asked about earlier, but it looks like there's evolution of thinking that's in the future and the ADA might be moving differently on some of these things or one of the groups. So I am aware of that and I think I'm following the conversation so far. I don't really know how we would do conditions, so I'm kind of avoiding that one. I think it's yes or no for me a little bit because I'm trying to figure out how we would do conditions in this one. So I think I could be convinced differently just to share.

Josh Morse

And that was slide 53. Is that right, Val? I have that if you want to see it, Janna. Or if Beth wants to share it.

Janna Friedly

Sure. And Chris?

Christopher Chen

Oh, I just want to add, and I don't know, Beth or Val King, if you guys are able to comment, but this wasn't necessarily depicted on the slides, these recommendations did come with different levels of evidence and different strengths of the recommendations. And there was a comment before that the conversation today kind of led people to kind of conclude one way or the other. And I just want to, yeah, as you said, Janna, the charge of the committee really is to focus on the evidence, including what was presented and so I think that's especially relevant when we're thinking about the individuals not on insulin.

Janna Friedly

Yeah, it feels like to me that this is an area that may be evolving and when we rereview this in a year or two or when it comes back around that there might be additional evidence. But to me, it seems clear that there's clear that there's evidence, at least as it is right now, doesn't, isn't there? The way I'm interpreting it. Val?

Luke Wander

I think this is last year's, isn't it? For the ADA, just for what it's worth.

Valerie King

Yeah, so if you go forward in those slides, this was the report with the cutoff of the date that we used. And then.

Val Hamann

Josh, sorry. These are the old slides. Sorry to interrupt, Val. There were slides that were sent yesterday.

Josh Morse

My bad. Thank you. Are they in the folder?

Val Hamann

Yeah, they're there. They are in the TAC folder.

Josh Morse

Okay. Well, it says updated even. Is that the one?

Val Hamann

Yep.

Beth Shaw

I mean, I think you're exactly right. The guidelines themselves are kind of moving Further, you know, and as we know with guidelines, they're based on evidence, but obviously then there's that whole discussion you know, with the experts you know with clinical input, patient input um so. But yeah, they're moving more into that consider offering and it is a weak recommendation.

Valerie King

Yeah. Yeah. And, you know, I would also just say in response to Chris Chen's um, comment that not all guidelines are created equal. If you were to look in the report on page 60, there's a table that lists out those guidelines for this population and of those guidelines, many of them are of good methodologic quality. Most of them are. The ones that are not are the American Association of Clinical Endocrinology the ACCE and the ADA. So ACCE is of poor quality for both of their guidelines and then ADA was a fair methodologic quality. So just there's some good work in this area and some that are more expert opinion and consensus based.

Christopher Chen

Thanks, Val. And even within any given clinical practice guideline, there were different levels of support for them.

Valerie Kin

Oh, yeah.

Christopher Chen

And some of them are graded A, B, D, A, A, B, C. Thank you.

Valerie King

Yeah. Okay. Yeah. Tue, true. You see that a little bit with the with this top part under oral therapies with the newer ADA, the two 2025 ADA where it's consider offering instead of do it.

Janna Friedly

Yeah.

Valerie King

It's just a lower level of strength and certainty of the recommendation.

Janna Friedly

Okay. Any other discussion? I wonder if we should do the straw poll one more time to see where we're at now after the discussion. And then.

Val Hamann

Would you like a straw poll on all of them or?

Janna Friedly

No, no, I, that last one yeah.

Val Hamann

Just on insulin? Okay.

Janna Friedly

Okay, so that discussion does look like it changed the direction of the decision there. So I think that that covers all of the straw poll decisions, I think, and the wording, I think we now, now need to just take a draft, I mean, take a take a poll on the poll on draft decision with wording for coverage with conditions.

Right, Josh?

Josh Morse

Yeah, so this would be a vote to over, cover with these conditions, or not cover.

Janna Friedly

Yeah.

Josh Morse

That can be your final draft vote if you're ready for that, if these conditions look right to you.

Janna Friedly

And so that would so these, so we could just do it with this and that would we don't need to we don't need a separate one for not on insulin because that's.

Josh Morse

Oh, that's up to you. If you think.

Janna Friedly

Because that's covered under here. I mean, as it's written here, this excludes not on insulin as it's written here, so we don't need a separate vote for that?

Josh Morse

Correct. Right. Yeah. And yes.

Janna Friedly

Okay. Yeah. Okay, so I just want to make sure I'm clear.

Josh Morse

No, no, it's okay. Yeah, I was thinking back to the scoping document where with a scoping document is phrase non-intensive insulin therapy so yeah, it may be best to break it into two votes and then if you do if your vote, you just did a straw vote, if that vote changes, that outcome changes, then you'll go back to developing those criteria for that.

Janna Friedly

Okay. Okay.

Josh Morse

So yeah, let's do it that way. That's a more pure way to do it.

Janna Friedly

Okay, that sounds good. Yep.

Jonathan Staloff

Question.

Josh Morse

Sorry, Val.

Janna Friedly

Yeah, Jonathan.

Jonathan Staloff

I'm just thinking back to, I forget his name, but the gentleman from Regence who often joins us about specificity of language. The word target hemoglobin A1C caught my attention. I feel like there's probably shared communal targets like less than seven for people under a certain age and less than eight for people under a certain age but I wasn't sure if we needed to achieve greater specificity for what we mean by target hemoglobin A1C?

Luke Wander

I can weigh in here a little bit, I think. I suppose one upside to leaving the language this way, you could contend that there are some clinical contexts when the A1C target that is the most conventionally the target doesn't make a lot of sense for example, older folks with a lot of comorbidity. So doing it this way would allow the clinician a bit more latitude in what was to be done. Also, then you wouldn't have to think about different thresholds in the context of pregnancy.

Jonathan Staloff

Thank you.

Janna Friedly

Okay, so Val, you'll get the vote's up.

Val Hamann

Yes. Did you want to, how we've done it previously. Vote on the proposed criteria, the yes, no, and then we can go into the final vote.

Janna Friedly

Sure.

Val Hamann

Okay. Okay, so seven yeses and one no. And then this one is this one not on insulin.

Josh Morse

We do not have criteria for this population, right?

Janna Friedly

So that we don't have criteria. Yeah, this was a no coverage decision.

Josh Morse

Right.

Val Hamann

And then here's the pregnancy.

Janna Friedly

And this was a cover, this was a cover unconditionally.

Josh Morse

Yes, the language reads individuals who are pregnant who have type 1 or type 2 or gestational diabetes.

Janna Friedly

So do we need to do this vote then?

Josh Morse

I think technically there are criteria you have to have diabetes.

Janna Friedly

Okay. Okay, sorry. I'm just not right.

Josh Morse

That's okay no I, I.

Val Hamann

Okay, so all are seven to one. Are you ready to move on to final vote?

Janna Friedly

Yeah, I think so.

Val Hamann

And did you want to vote on the Insulin they're not on insulin or keep it to keep it to children and adults not on intensive insulin treatment and then the pregnancy.

Josh Morse

The language, I'm looking at the screen with language. So the language is individuals with type 2 who are on insulin therapy.

Val Hamann

So you want me, should I move pregnancy into this one?

Janna Friedly

No. It.

Josh Morse

No.

Val Hamann

No? Okay.

Janna Friedly

It's, it's for adults and children with type 2 diabetes on insulin.

Val Hamann

Do you want me to take that?

Christopher Chen

Can I make a suggestion because the um the previous polls, I feel like we should just mirror the previous polls?

Val Hamann

Yeah, we definitely can. Yep.

Christopher Chen

We're done. Okay. Right, Josh? If there's a pull on criteria and then a pull on finalizing the decision. Should they be mirrored?

Josh Morse

That probably makes sense. Yeah.

Christopher Chen

Okay.

Val Hamann

So we were comfortable with these three?

Laurie Mischley

I just, again, we're just getting into that not on intensive insulin means oral.

Josh Morse

This is more broad, right? So you refined this into two populations.

Val Hamann

Okay, so we just, we want to take the intensive out and then we'll just do the insulin.

Christopher Chen

Well, sorry, I understand that that is the slide 27 technically includes those who are on just insulin. Sorry, those who are on non-intensive insulin and those who are not on any insulin but I think that's also how you guys voted for all of the above polls. That's where you kind of took your straw poll that's on the evidence. That's where you took your vote on the criteria. That's what this language was, wasn't it?

Laurie Mischley

Right. Just to reflect the wording of what we're proposing is for people on insulin as soon as you get the not on insulin, it just gets a little. Anyway, it's for clarity, right? I think we're voting that anyone on insulin is eligible for the decision we're about to make, right?

Janna Friedly

I think we're getting a little bit turned around here. Can we go back to what the are they are there previous slides that show what we. Yeah, so I think the issue is that when we originally did the straw poll vote, the wording was not on intensive insulin treatment and then when we went to go do the coverage criteria, we realized that we needed to split out the, the um oral people on oral or not on insulin and, and so our intention is to split those out. So I think that this, this boat needs to reflect that as Laurie is saying. In order to be accurate and consistent with the criteria that we came up with. Does that make sense, Josh?

Josh Morse

It makes sense to me. I think if you vote on this one. I'm sorry, Val, if you could stay on that one. Persons not on insulin therapy, you do not have criteria for this. If your vote is consistent with your straw poll vote, which was majority not covered then you will have a final draft decision on those not on insulin adults and children type 2. The next vote would be the vote for those with type 2 on insulin therapy or, or you can do the pregnancy vote anyway the other type 2 vote will be those on insulin therapy. So yes, I think two votes there, three votes total. And you'll have clarity on your decision and we'll have a record of the vote.

Janna Friedly

Sorry, that's confusing. End of the day. Okay. It is.

Josh Morse

Yeah, it's confusing. There's a lot of different logics here, I think, at play.

Val Hamann

Okay. We have eight not to cover. And then for are not on intensive insulin treatment.

Josh Morse

I think we need to change this one to on insulin therapy, on insulin treatment.

Val Hamann

Just on insulin or on Okay. Did you want therapy or treatment?

Janna Friedly

It doesn't matter, just on insulin is fine.

Val Hamann

Okay.

Janna Friedly

No, it's still showing the, the wrong language on the poll.

Val Hamann

It doesn't say on insulin. Interesting.

Janna Friedly

No, it says not on intensive.

Val Hamann

Let’s try this again. Is that showing up now? Okay. Okay, covered with conditions for seven and one is covered unconditionally. And now for pregnancy.

Janna Friedly

And Josh, is this the right wording? For pregnancy, this includes insulin just not using insulin? Was the insulin included? It was type 1.

Josh Morse

This should be just pregnant, pregnant people with type 1, type 2, or gestational diabetes.

Christopher Chen

Yes.

Josh Morse

No mention of insulin.

Janna Friedly

Yeah, this wording isn't correct.

Josh Morse

Chris, do you agree with that? That's how the current decision is written.

Christopher Chen

Yeah, I think it could go either way. Yeah, I think that's fine.

Janna Friedly

So.

Josh Morse

Yeah, thanks for catching up.

Val Hamann

Let me know if it does not update the wording for you all.

Janna Friedly

Yeah, that's better.

Val Hamann

And eight to cover unconditionally.

Janna Friedly

Ooh, we made it. Okay. So, Josh, we're set then for the coverage language, the cover with criteria language Or do we need to okay.

Josh Morse

Yes. Yes. Let's just go back and I'll, we'll look at this again. That last vote is fine it is essentially covered with conditions but, but it's technically there are if you're pregnant it's covered if you have diabetes of one of the three types.

Janna Friedly

Yeah, no, I meant the other one, the cover with conditions one. We need to now cover? Do we need to now do a last vote with cover with conditions or because we already?

Josh Morse

No, you're done.

Janna Friedly

We're done. Okay, thank you. Okay, good.

Josh Morse

Yes. No, you've just voted on the three aspects of this of this decision. Yeah.

Janna Friedly

Okay. I just want to make sure. Okay, sorry. My brain is a little turned around.

Josh Morse

Understandable.

Janna Friedly

Okay, great. So now we just need to look at the guidelines and, so 63, page 63 of the report. Yeah, so we are consistent that we're covering if they are taking if for adults with type 2 diabetes taking insulin of any kind. The only difference is that we have we have covered in people with pregnancy. And then we've discussed the, the clinical practice guidelines.

Josh Morse

Well, can I just challenge you a little bit on that? Because I'm reading this and I'm looking at the report. It says, or have a history of problematic hypoglycemia, so it sounds Medicare may cover it for people who don't necessarily take insulin but have. Am I reading that right? Don't have hypoglycemia. Do you have hypoglycemia but aren't taking insulin?

Janna Friedly

Continues to occur if taking again. That's a good question.

Josh Morse

And it's okay if you're different. Your rationale is based on a different evidence base or the current evidence.

Janna Friedly

Yeah. Yeah, that does. Sorry, I'm just um. Let me pull up the page 63.

Josh Morse

I have that open if you'd like me to share it.

Janna Friedly

Yeah, that would be helpful. Yeah, that's all it says. I thought there was going to be more on there. That's it. That's interesting. So that is a little bit different.

Beth Shaw

Yeah, just at the bottom of page 63. It says there the new Medicare policy allows individuals with diabetes who do not take insulin but have a history of problematic hypos to qualify.

Janna Friedly

Okay. Okay, so I think we just we have to acknowledge that that is slightly different. So that is consistent with the um a little bit more consistent with the evolving guidelines, but not based on the evidence that we, we reviewed today. Okay. Anything else before we, before we adjourn today?

Josh Morse

You did look at the guidelines and you did compare your decisions essentially already to those guidelines. So I think you've covered the bases there as far as the NCD and the Professional Society Guidelines. So I think you've hit all those marks. Thank you.

Janna Friedly

Okay, great. Well, I want to thank our clinical expert for being here today, Dr. Wander, and thank everybody for their participation. We got through a lot of material today. I think we really covered a lot of ground and had some really good discussion today on some difficult topics. Appreciate everybody hanging in there today. And we'll see you at the next meeting.

Tony Yen

Washington State Health Care Authority

Thanks, everybody.

Josh Morse

Thank you.

Laurie Mischley

Thanks, Janna. Bye, everyone.