A CMS Medicare Administrative Contractor
https://www.NGSMedicare.com

## ANTHEM INC

### Moderator: Dr. Ola Awodele

***October 26, 2023***

## *12:00 pm ET*

Coordinator: Welcome and thank you all for standing by. At this time, I would like to inform all participants that your lines have been placed on a listen-only mode until the comments section of today's conference. Today's call is also being recorded. If you do have any objections, you may disconnect at this time. And I will now turn the call over to Dr. Awodele. Thank you. You may begin.

Ola Awodele: Thank you. Good morning - Good afternoon, everyone, and thank you for joining us for National Government Services J6JK Open Meeting. As it's showing on the screen, if you are only in via WebEx, you will definitely have to call in using the call-in number that is showing on the screen. We do have - can you move to the next one? Slide. Okay.

Just to let everybody know, this call is being recorded and will also be transcribed. The CMDs for NGS are me, Ola Awodele; Dr. Stephen Boren; Dr. Mark Durden; Dr. Gina Mullen; Dr. Greg McKinney; and Dr. Ella Noel. So, we have four draft LCDs to be discussed in today's meeting, as showing up there. The first one is trigger point injection. We have pain management and injection of tendons sheaths, ligaments, ganglions cysts, carpal and tarsal tunnels. We have fluid jet system treatment for LUTS. And we have implantable continuous glucose monitors. None of these LCDs or drafts are new. These are being brought to the open meeting as a result of changes that have been made in then from valid reconsideration requests.

Next slide, please. So, the first draft LCD is going to be trigger point injections. And I'd like to invite Dr. Marc Durden to take the floor. Dr. Durden?

Marc Durden: Thank you, Dr. Awodele. Trigger point injections have been described as an overall safe and effective modality for the treatment of pain associated with myofascial trigger points. There is moderate evidence to support the role of trigger point injections for myofascial pain, which is related to the presence of a trigger point. Nevertheless, there are no high-quality randomized controlled trials or large observational studies to support these. And most studies have investigated trigger point injections are not blinded, lack controls, they lack standardized patient selection and assessment of improvement, and they have small sample sizes and lack long-term follow-up.

Trigger point injections will be considered medically reasonable and necessary to treat myofascial pain caused by trigger points when all of the following requirements are met: that there's a focal area of pain in the skeletal muscle; two: that there is clinical evidence of a trigger point defined as a point in the skeletal muscle that is associated with at least two of the following findings. The presence of a hyperirritable spot or taut band identified by palpation and possible referred pain, and the physical examination identifies a focal hypersensitive bundle or nodule of muscle fiber harder than the normal consistency with or without a local twitch response and referred pain.

And there is non-inva - sorry, non-invasive conservative therapy has not been successful as first-line treatment, or the movement of the joint or limb is limited or blocked, or the trigger point injection is necessary for diagnostic confirmation.

Repeat trigger point injections of previously injected trigger points will be considered medically reasonable and necessary to treat myofascial pain syndrome when all of the following requirements are met: Number one: that there is a positive pain response from the most recent trigger point injection, which is defined as providing consistent minimum of 50% pain relief of the primary index pain after the trigger point injection and measured by the same pain scale and baseline on post-injection; And number two: consistent pain relief from the most previous trigger point injections lasting at least six weeks. And the myofascial pain has recurred and is causing functional limitations measured by a functional scale obtained at baseline and after the trigger point injection, which demonstrated at least 50% improvement from the previous trigger point injection.

Now, the requirements for the trigger point injections will be: One: the patients must be part of an ongoing conservative treatment program and documentation to support the patient is actively participating in a rehabilitation program, a home exercise program, or a functional restoration program in the medical record. Two: that there is at least six weeks' duration between trigger point injections is - sorry, there is at least six week's duration before a trigger point injection is repeated in the same location.

Three: the trigger point primary index pain must be measured prior to the injection at the beginning of the trigger point injection session. Four: the post-procedure pain level must be measured after the trigger point injection and at the conclusion of the session using the same pain scale which was utilized at baseline. Five: when documenting the percentage of pain relief from the primary or index pain and compared to the post-injection pain levels, it is insufficient to report only a percentage of pain relief and or nonspecific statements about the duration of pain relief.

The documentation must include a specific assessment of the duration of relief being consistent or inconsistent with the agent used for the injection and the specific dates the measurements were obtained using the same pain scale which was utilized at baseline; Five - Or Six: when documenting the ability to perform previously painful movements and activities of daily living, ADLs, it is insufficient to provide a vague or nonspecific statement regarding the improvement of previously painful movements and activities of ADLs.

The documentation must include a functional assessment to show clinically meaningful improvement with painful movements and ADLs. If this metric is used to justify the efficacy of the trigger point injection, providers must use the established and measurable goals and objective scales to assess functionality and the ADL measures.

Now, I'd like to discuss the limitations. First: there are no more than three trigger point injection sessions will be reimbursed per rolling 12 months. Next, a trigger point injection involves the use of local anesthetic and does not include the injection of biologicals. For example, platelet-rich plasma, stem cells, amniotic fluid, or et cetera, and the injections of any other injectants.

Next, it is not considered medically reasonable and necessary to perform trigger point injections into multiple muscle groups in different anatomical regions during the same session. Next number is that it is not considered medically reasonable and necessary to perform multiple blocks, for example, spine - epidural spine injections, sympathetic blocks, facet blocks, et cetera, during the same session as the trigger point injection.

Next number is that trigger point injections for the treatment of headache, neck pain, or low back pain in the absence of a trigger point in - or an actual trigger point, or the diffuse muscle pain, or a chronic pain syndrome, or a lumbar sacral canal stenosis, or fibromyalgia, or malignant - nonmalignant multifocal musculoskeletal pain or complex regional pain syndrome or sexual dysfunction and pelvic pain or whiplash or myo - neuropathic pain or a hemiplegic shoulder are considered investigational and therefore not considered medically reasonable and necessary. Continuing with the limitations, the use of fluoroscopy or MRI guidance for the performance of trigger point injections is not considered reasonable and necessary.

Next number is that the use of ultrasound guidance for the performance of trigger point injections is not - sorry, is considered investigational. And trigger point injections used on a routine basis, for example, on a regular, periodic, or continual basis for patients with chronic nonmalignant pain syndromes are not considered reasonable and necessary, or considered medically necessary. So, that concludes the outline of the LCD that is being developed and is a draft for the trigger point injections. And I'd like to ask the operator to open up the line for Dr. Boris Abayev, who wants to make a comment.

Boris Abayev: Yes. Look...

Coordinator: Dr. Abayev, your line's open.

Boris Abayev: Yes. Okay. Can you hear me now, Please?

Marc Durden: Yes.

Boris Abayev: Are you able to - Okay. I mean, this was total surprise for me. And I'm looking into that, and I'm saying that this is one of the most commonly used tools for the doctors who can help in a time of need to the patient. Now, you guys think, no,

you're not going to have no longer this kind of tool. So, you - three injections over a year, you stop your treatment after three, and that's it. For the whole year, this patient is not going to get any treatment. So my question is, would be - so, imagine this is somebody close to you, a relative, somebody who really needs help.

So, after three - so, I offered first injection, 30% improvement; second injection, 50% improvement; third injection, 70% improvement. And I have to stop now and tell the patient, and I'm so sorry, that's it, this is all I can do for you. And the patient is going to reply to me, hold on a second, Dr. Boris, the treatment is working, what's wrong, why?

Oh, the Medicare says so, or CMS saying so, there is a new policy. Patients don't care about these policies. If the treatment is helping to the patient, you go ahead and you continue and complete the treatment to the patient's satisfaction until the patient is 100% pain-free and fully functional. That's the key word, functional, why?

After the first treatment, the patient is telling me, listen, I couldn't pick up the keys from the floor. I dropped it accidentally. I couldn't. Now with your treatment, I'm able to bend and pick up the keys, and you say, no, no, no, no, that's vague. That's baloney. I don't like that. You give us concrete functional statement, concrete - hold on a second. This is activities of daily living. The patient may drop keys, passport, money, anything, and he has to be able to bend from the floor and pick it up. And he's telling you, yes, I'm able to pick it up, I'm happy, I'm satisfied.

And we have to say, no, no, hold on a second, no, no, we have to measure it. What is the range of motion with the arm? What is the range of motion with the spine? Is that more than - I mean, to me, you made this not only complicated, you made it impossible to use this draft of a trigger point injection. You made it impossible. So, basically what you're saying is, and again, I don't want to be emotional about this. You're saying that, look, you're going to have a limited amount of trigger point injection and is nobody gives a shoe about this patient is getting better or not getting better. Three injections, bye-bye for the whole year, for 12 months.

I don't know who is giving you this information, and I'm so sorry. I've been practicing pain management for 25 years, and I'm a musculoskeletal pain fellowship trained doctor. And I see thousands of patients getting improved, who are completely recovered, and I urge you to please go onto Google, onto Internet, and put my

name, and see what people are saying. You know, I think that's the most important thing would be if the patient is improving, if the patient is - the pain is going away.

I have cured a migraine headache for 32 years. Completely cured within five or six visits. Cured. So, how can I tell that patient, no, no, no, no, three injection periods for the whole 12 months? No. Can not. Impossible. And also, also, you're not mentioning here, by the way, what if I'm using just lidocaine only? That's legal, that's official, that's one of the treatment options, just only lidocaine or only buprenorphine, only any local anesthetic. So, I don't need a restriction or every injection, you have to wait six weeks now for the second injection to be done.

That's - I don't know who is giving you this information even. And I'm so sorry, I want to challenge those people. I want to come in face-to-face, meet with all of you guys and the people who is giving you this information. This is not only wrong, this is very, very, very wrong. You know, I mean, you're pushing all of us, just close your office, get the hell out of from town and don't practice medicine anymore. That's what I'm understanding from all this.

This is wrong, this is not the way it's supposed to be. And to why do I have to wait six weeks? Lidocaine is generally pain-free. The lifetime of lidocaine is one and a half; two hours, of half-life. One and a half; two hours. So, I don't anticipate any - and the reason I use lidocaine only because vast majority of my patients are diabetic, high blood pressure.

And I don't want to use steroids which would increase as a side effect blood pressure, which would increase blood sugar, which would, you know, elderly women, osteoporosis, which would contribute to the osteoporosis, washing out calcium from the bone. I don't want to use those kind of steroids on those patients. I want to play safe. I'm using lidocaine only. What's wrong with me using lidocaine and offering this injection once a week? What's wrong with that? Tell me this is illegal. Tell me this is wrong. Justify that to me, please.

And you cannot justify this to the patient. If the patient is coming and telling you - and I'm so sorry - Yeah, if the patient is telling you, look, your treatment is working, continue please, continue. Why should I stop and say, no, no, no, no. Once every six weeks, I have to give you a second one. You have to wait six weeks. Why wait? You

know, I'm in pain. My pain is getting better. Why don't you offer me a second shot, third shot, finish this treatment off, the course of treatment?

And again, I have people who I cured within one visit. Boom, 100 % pain is gone. I have people who I cured within two visits. I have people who I cured within five visits. I have people who I cured within seven. It is very difficult to say how many visits this patient may need. It is supposed to be, you know, each time, you know, if you see that the patient is improving, that's your justification to continue the treatment. And I'm - since I'm using lidocaine only, it's harmless. Generally, lidocaine used worldwide. It is harmless, it is the most safest medication in the world consider. Why do you - would you restrict me once every six weeks to use lidocaine only? Why? What is the reason? What's your justification?

And also, why do I have to wait until the improvement is more than 50%? No. Some of my patients come and say, look, 30% better. Some people come and say, look, 20% better. Any improvement I get, that gives me justification to continue the treatment. Otherwise, what is - what am I doing then? Am I a doctor or I'm somebody else? I'm supposed to be patient's representative. I'm a patient advocate, to help the patient in a time of need. If the patient is improving 20%, so I tell the patient, so, it looks like your improvement is going to be slow 20%, the next time it's 40%, and then 60%, and then 80%, so within five years this pain should be gone. Right? So...

Marc Durden: Well, Dr. Abayev?

Boris Abayev: Yeah. Please. I'm so sorry. I got carried away. I'm sorry about that.

Marc Durden: That's okay. You're fine. First of all, I'd like to thank you for taking care of Medicare patients. And I do appreciate the fact that you are an advocate for those patients. And I appreciate your impassioned comments. What I would request is that you submit these comments in writing and provide any medical literature for references that you feel would be directly applicable to your comments and addressing some of the issues that you have brought up, but we would need to have those comments placed in writing, so I'd appreciate it.

Boris Abayev: I did that, but they wouldn't accept my comments, why? Because there is already a draft, they're saying, that there is already a draft, so we cannot accept the draft. Hold on a second.

Marc Durden: What was...

Boris Abayev: I didn't - I was not aware about the draft when I submitted my comments. I was not aware of those drafts.

Marc Durden: Okay.

Boris Abayev: But now I'm submitting my comments. My comments are there, but they're not...

Marc Durden: Okay.

Boris Abayev: ...being looked at. Nobody's looking.

Marc Durden: Thank you. Well, I'd appreciate, you know, if you could submit that in the format of this open meeting, then it would help us with the LCD development process that we're required to go through.

Boris Abayev: Okay, you mean like do it on Internet, like on the Web site?

Marc Durden: Yes, there will be a place for you to make the comments to - for this draft following this open meeting and emphasizing points that you brought up today.

Boris Abayev: Okay. And also, would you be able to give me the person in-charge who I communicate directly, because this is about patient's care. It's not about bureaucracy, it's about patient's care. So, I need to be able to - since you are binding, twisting my arms behind my back and saying, look, now you're going to behave, you're going to be doing those injections three, four, five times or seven times. No, three times for the year. For the - This is such - and I apologize if I offended somebody by saying this. This is such a nonsense.

Imagine this is your father, this is your mother, that's your family member, that's your wife, and I'm offering my treatment, and somebody's telling me, no, no, no, no, no, no, stop right there. How many, three, stop, that's it, for the whole year. Now, patient, you're going to have to wait another nine months or ten months until this year, calendar year, is over, and January of next year, I'm going to be able to. This is

such a baloney, and I'm so sorry. I apologize for using this word. I'm so sorry that - I'm sure that you're getting offended by me saying that, but hold on a second, who came with those ideas. Who brought this issue up? Who even came up?

I tell you this, I'm challenging you officially on the Web site right now. Show me one article which says no more than three injections over the year. Show me one article which says the - improvement must be more than 50% after the first visit. Show me one article. Show me just one. I'm challenging the whole team of yours. Show me one article. You're not going to be able to show me one single article. One, you're not. Why? There is no non-exist. And somebody is just - this is wishful thinking for someone. Wishful thinking, oh, you know what, let's do this, let's do that.

Yeah, I mean, I understand that if you tell me that the board is trying to save up some money for the Medicare, yeah, I would understand that. But not - I'm not playing games here with that money of the Medicare. I'm not playing games. Look, I'm trying to help them. And also, if the patient is cured, let's say I saw this patient five times, pain is gone.

Marc Durden: Dr. Abayev...

Boris Abayev: Yeah, I'm sorry.

Marc Durden: ...if it's getting circuitous. And so what I would like to simply just admonish you again to submit these comments in writing, the ones...

Boris Abayev: Okay.

Marc Durden: ...that you've made today. And please provide any medical literature and references that you would like to see the - how they are directly applicable to the comments that you've made.

Boris Abayev: Okay.

Marc Durden: Okay. Thank you, sir.

Boris Abayev: And do you think I could be able to speak directly to somebody in-charge, the person in-charge?

Marc Durden: Well, I think that's outside of the format of this, obviously. This isn't a debate or anything. This is for public comment. And so that's what we're doing today. Later, outside of the LCD process, and after it's formalized, there are some other processes that I can refer you to in the Program Integrity Manual, Chapter 13, which gives you remedies to address some of these additional concerns that you may have, as we move through this LCD development process.

Boris Abayev: Mm-hm. Yeah. But just one more comment. Just looking at this, all insurance companies looking up at the Medicare right now. And guess what they're saying already? Oh, you know what, no more than three injections a year. Same thing, they're already repeating that to me, already. In your case, it is a draft. Guess what? The insurance companies who I work with, they already tell me, no, that's not a draft. That is already a law. You cannot do more than certain amount of injections. You cannot do this, you cannot do that. Basically everybody, every insurance company twisting my arms behind my back and telling me, you cannot treat the patient that way.

So, basically I'm being told how to treat my patient. And I'm willing to dispute that. I mean, if somebody is a medical doctor, let's face-to-face speak, not over the Internet. Let's speak face-to-face. Let me come over to your place. Let me bring the literature. Let me prove my point to you. And let me bring like 10, 15, 20 patients. And you ask them those questions and look, what's going on, you know, I mean, what do you think about this?

Marc Durden: Well, the forum for this open meeting doesn't allow for that, but certainly, as I alluded to, that there are other processes for the policy development. And we will - I can follow back up with you regarding that policy information.

Boris Abayev: Okay.

Marc Durden: Okay.

Boris Abayev: Okay. Yes. Thank you very much. Yeah I'm...

Marc Durden: Thank you, Dr. Abayev.

Boris Abayev: Thank you so much for (unintelligible).

Marc Durden: I'd like for you to open the line up for anybody else that would have any comments.

Coordinator: Thank you. At this time, if anyone would like to make a comment. Please ensure that your phone is unmuted. Press Star 1, and record your name clearly when prompted. If you need to withdraw your request, you may press Star 2. Again, to make a comment, please press Star 1. It will just take a moment for any comments to come in. And at this time, I am not showing any comments.

Marc Durden: Thank you, operator. I'll turn the time over to our feeding coordinator, which is Dr. Awodele.

Ola Awodele: Thank you, Dr. Durden. And at the end of the meeting, I - the very last Slide will show how to submit comments in terms of where to submit them, what email box and stuff to send things to, so stay tuned. Next, can we move to the next Slide, please? The next track that we're going to discuss is DL33622, which is pain management, injection of tendon sheath, ligaments, ganglions cyst, carpal and tarsal tunnel. Dr. Durden?

Marc Durden: Thank you, Dr. Awodele. The change that is occurring with this LCD for pain management is simply the removal of the trigger point injection language that was previously there. The new LCD 33662 for pain management will otherwise be unchanged, except for that -removal of that trigger point injection language. And what we'll do now is, turn the time open to or have the operator seek any additional comments. If anyone would like to make comments about this draft LCD.

Coordinator: Thank you. And as a reminder, that is Star 1, if you would like to make a comment. One moment to see if we have any comments come in. And there are no comments at this time.

Marc Durden: Thank you, operator. With that, I will turn the time back over to Dr. Awodele.

Ola Awodele: Thanks again, Dr. Durden. We have the next draft, it's DL38367, Fluid Jet System Treatment for LUCS/BPH, Dr. Noel. Dr. Neol, we can't hear you.

Coordinator: Dr. Noel, your line might be muted.

Ella Noel: Sorry about that. We received a reconsideration this year. And in this request, they asked to remove the limitation of an age greater than 80. The literature that they submitted was reviewed. Several real-world studies that included men greater

than the age of 80 were submitted. While the quality of the evidence is weak, it does demonstrate the utilization of the procedure in this age population. Significantly, the five-year water trial data shows positive long-term outcomes and a less invasive approach in the octogenarian population may be beneficial. Therefore, the limitation has been removed from this policy. At this time, we'll take any comments.

Coordinator: Thank you. As a reminder, if you'd like to make a comment, please press Star 1. One moment to see if we have any comments come in. And there are no comments at this time.

Ella Noel: I will turn it back over to Dr. Awodele.

Ola Awodele: Thank you very much, Dr. Noel. All right. The next draft LCD is DL38623. It's Implantable Continuous Glucose Monitors, also known as I-CGM. This is a collaborative proposed LCD, and we were modifying the coverage criteria for implantable continuous glucose monitors based on the best available evidence. We received a reconsideration request to evaluate whether published evidence-based continues to support the equivalency of Implantable Continuous Glucose Monitors and Traditional Subcutaneous Continuous Glucose Monitors in the management of adult diabetes mellitus.

The evidence did suggest that for adults manage - patients managing diabetes mellitus, ICGM performs with little to no difference in diagnostic accuracy, patient-reported efficacy outcomes, objective efficacy measures, and device procedure-related adverse event rates when compared to subcutaneous CGM. Furthermore, evidence suggests that the optimal patient selection criteria for ICGM and for subcutaneous CGM are largely overlapping. Although limited in quality, this evidence base s sufficient to determine non-inferiority or equivalency, if you would, between ICGM and subcutaneous CGM.

Additionally, although no direct evidence was identified that assessed ICGM utilization among non-insulin treated patients with diabetes complicated by hypoglycemia, there is still adequate evidence to infer equivalence with subcutaneous CGM systems among this population based on the total totality of evidence that we reviewed. Firstly, among the approved indications for ICGM, the U.S. Food and Drug Administration has cleared Eversense to provide glucose trend

information and to provide alerts for the detection and prediction of episodes of low blood sugar, that is hypoglycemia, and high blood sugar, otherwise known as hyperglycemia.

Also, although outside the scope of the main evidentiary review, three publications were identified via bibliographic cross-referencing that evaluated subcutaneous CGM benefit among this group of patients. One of these three trials concluded that among non-insulin-treated patients with diabetes mellitus complicated by hypoglycemia, subcutaneous CGM system resulted in a significantly greater reduction in hemoglobin A1C than SMBG.

The other two studies suggested CGM systems were able to detect hypoglycemic events among non-insulin-treated patients that were overwhelmingly undetectable by symptoms of SMBG. We did receive a request to present on this draft LCD. Can we go to the next Slide, please? From Senseonics, and so we have Dr. Francine Kaufman on the line. Can you please unmute her line, so that she can start the presentation. Thank you.

Coordinator: Yes. Dr. Kaufman...

Ola Awodele: Dr. Kaufman.

Coordinator: ...your line is open.

Francine Kaufman: Can you hear me?

Ola Awodele: Yes, we can.

Francine Kaufman: Oh, good. Thank you very much. So, my name is Dr. Francine Kaufman. I'm the Chief Medical Officer at Senseonics and also a Distinguished Professor Emerita of Pediatrics at the University of Southern California. I also happen to be the Past President of the American Diabetes Association. And I continue to see patients myself in my clinic in Los Angeles. Next Slide, please.

I do have a conflict of interest. I am the Chief Medical Officer of Senseonics Incorporated. The only fully Implantable CGM that's available on the market in the United States. Next Slide. Just briefly to describe the system. So, there's three components. There's a fully implanted, very small, 3/13 millimeter sensor that's placed in the upper arm by a trained and certified healthcare provider in a very

brief in-office procedure. On top of the sensor lies a transmitter that powers the sensor, gets the raw signal from the data from the sensor, and then calculates the glucose value, transmits this to a app on the patient's smartphone where the glucose values are shown every five minutes, as well as alerts can be elicited both visually as well as auditory if there's an aberration of the glucose value.

And in addition, the smart transmitter also elicits right on the arm of the patient, a vibratory alert for hypo and hyperglycemia. We are measuring glucose in the interstitial space through a fluorescent technology and we've been approved by the FDA since February of 2022 for adults with diabetes. Next Slide, please.

So, we are in support of the draft LCD that modifies the beneficiary to be not only those treated with insulin three or more daily administrations a day or using a subcutaneous insulin pump, but it expands this criteria to allow those on basal insulin only. In addition, it also allows for the Implantable CGM to be used in those who have a history of problematic hypoglycemia. So, this updated criteria for coverage of Implantable CGM better reflects the current clinical evidence and standards for reasonable and necessary use of CGM. There's a robust evidence in the medical literature, supporting this position. There are a number of randomized control trials showing the benefit of CGM in type II diabetes patients on basal insulin only.

There are three systematic reviews with meta-analyses that showed CGM use in patients with type II diabetes compared to using finger stick glucose measurements was also associated with significant reduction in hemoglobin A1C. And there are two prospective clinical trials showing that the use of a CGM in those experiencing significant hypoglycemia allows for improvement in hypoglycemia rates. In addition, the major professional diabetes associations in the United States have made favorable recommendations for the use of CGM, and in particular for patients with type II diabetes on basal insulin only.

Next Slide, please. So, Senseonics supports the draft LCD DL38623. The changes in coverage are in concert with the medical literature and positions of the major diabetes associations. The updated coverage provides parity to coverage criteria across all CGM systems, including those now with DME and making implantable with parity. However, we respectively request that NGS add all relevant ICD-10

diagnoses to DA58116, so both DME, CGM, LCD, and the Part B ICGM, the Implantable ICGM, have parity across ICD-10 diagnoses.

Next Slide, please. In our official comment submission, we have provided a list of 81 ICD-10 diagnoses codes, currently not included, but are included in the DME, CGM, LCD. So, this creates confusion among providers who are looking for consistency across covered diagnoses. And we do believe that it is essential that a number of ICD-10 diagnoses be added to the DA58116. These include diabetes mellitus due to underlying conditions with unspecified complications, type I diabetes mellitus with unspecified complications, type II diabetes mellitus with unspecified complications, and other specified diabetes mellitus with unspecified complications.

Next Slide, please. So, in summary, Senseonics appreciates NGS timely review of the implantable CGM, LCD to bring coverage criteria parity across all CGM systems. We support the updated coverage criteria included in the proposed LCD, and we request that the draft coding article DA58116 include the requested ICD-10 codes to ensure parity across CGM systems. And I thank you for your attention.

Ola Awodele: Thank you very much, Dr. Kaufman for that presentation. And obviously, we have this presentation at hand, so it will be taken as a submission in terms of comments. If there was any literature to support any of these that you want to send on our way that you don't see in our LCD as a reference, please feel free to do so. Thank you very much. Operator, could you please open the line, just ask if there is any other - if there are any other comments on the line at this time.

Coordinator: Sure. At this time, if you would like to make a comment, please press Star followed by 1. One moment to see if we have any comments. And there are no comments at this time.

Ola Awodele: Thank you. Can we go to the next Slide, please? Okay, so this brings us to the end of this open meeting. And as you can see, I'll - we'll talk about the official comment period of the L - the draft LCDs for DL33622, DL38367, and DL38623, the official comment period ends November 18, 2023. And for the trigger point injections, DL39662, the comment period ends December 1, 2023. What that means is you have until those dates to submit any comments in writing, accompanied by literature to support those comments. We would really appreciate that, in order for us to

consider these comments while we're drafting the final version of these LCDs. Can we have the next Slide, please?

So here's how you do it. To submit comments, you should - you must include conflict of interest disclosure, and you have options of sending it, you know, going to the webpage, click on the - to the LCD that - the proposed LCD that you have, click on the public comments button and submit your comments online that way. You can write an email and submit it to PartBLCDComments@anthem.com - at PartBLCDComments@anthem.com. Or you can send it by mail to National Government Services Incorporated LCD Comments, P.O. Box 7108, Indianapolis, Indiana, 46207-7108.

So, do we have any more Slides? Okay. So, this brings us officially to the end of this open meeting. We'd like to thank everyone who called in. Operator, you may disconnect at this time.

Coordinator: Thank you. That does conclude today's conference. Thank you all for participating. Participants, you may disconnect at this time.

END