Open Meeting: Glucose Monitors & External Infusion Pumps

Meeting Date and Time:	January 19, 2021
Facilitator:	Stacie McMichel
Location:	Virtual Meeting

Stacie McMichel *(0:03)*: Open Meeting for Glucose Monitors and External Infusion Pumps. For those of you that are scheduled to present your comments this morning, please make sure you have entered your audio PIN into your telephone keypad.

If you can hear my voice but you have not entered your audio PIN, you must hit the pound key and enter your audio PIN and then the pound key again. Just as a note, the audio PIN is located in the audio pane that is right to the right of the screen on the on the, on the GoToWebinar App. It is imperative that you do this so that we can unmute your line when it's your turn to speak.

And just as a note, we are experiencing technical difficulties with our open meeting CGS e-mail address.

If you are having any difficulties with meeting access, you may e-mail us directly at LCDReconJC. And that's L as in Larry, C as in Cat, D, Recon, R E C O N J C at CGSadmin. com, for support. I'll now turn the call over to Dr. Hoover for his opening remarks.

Dr. Robert Hoover *(1:14)*: Thank you, Stacie. Good morning and welcome members of the public and interested stakeholders to this virtual public meeting. I'm Dr. Robert Hoover, DME MAC Medical Director for CGS the Jurisdiction C DME MAC and one four DME MAC Medical Directors responsible for the proposed Glucose Monitors Local Coverage Determination.

We're here today to solicit comments on the proposed Glucose Monitors LCD. Following this Glucose Monitors proposed LCD public meeting, we'll continue with an open meeting for the External Infusion Pumps proposed LCD.

We will be recording the meeting today, audio only, and we'll have the recording posted on the DME MAC websites within a short time after the conclusion of the meeting. By signing in today you're giving your consent to the use of your recorded voice and comment. Please be mindful of sharing any personal health information in your verbal comments. We also ask that any comments made today also be submitted in writing to BGMLCDComments, that's plural, BGMLCDcomments@CGSadmin.com.

The comment period will close on Saturday, January, the 30th at 5:00 p.m. Eastern Time and details for submitting comments are also available on the DME MAC websites and at the end of this presentation.

We have several commenters registered to speak at this virtual meeting, Stacie McMichel, whom you just heard, one of our CGS Provider Outreach and Education staff, will be queuing the speakers. Only pre-registered commenters will be allowed to comment at today's meeting, but anyone can submit written comments to the address I mentioned a moment ago.

For those commenting, we'll be strictly enforcing the time limits in order to stay as close to the schedule as possible. We ask for that those that are on the phone, take a moment to locate your mute button. We ask that you mute your line, not place it on hold, when you're not speaking or if you have a sidebar conversation. Speakers should be prepared to begin their comments immediately when called upon.

Now I'll introduce the DME MAC Medical Directors.

Dr. Smitha Ballyamanda is the Jurisdiction A Medical Director at Noridian Healthcare Solutions, LLC. Jurisdiction A is comprised of 11 north-east States and the District of Columbia. She's a family physician with a specialty certification in Sports Medicine and has been a DME Medical Director for three years.

Dr. Stacey Brennan is the Jurisdiction B Medical Director at CGS Administrators. Jurisdiction B encompasses seven mid-western States, and she's a family physician who has been a DME Medical Director for 12 years.

Dr. Peter Gurk is the Jurisdiction D Medical Director at Noridian Healthcare Solutions, LLC. Jurisdiction D is comprised of 17 Western States and three U.S. territories. He's a Family physician and has been a DME Medical Director for 6 years.

I'm Dr. Robert Hoover, the Jurisdiction C Medical Director. Jurisdiction C encompasses 15 southeastern states, Puerto Rico, and the U.S. Virgin Islands. I'm an internist and I've been a DME Medical Director for over 20 years.

I'll now go over the highlights of the proposed Glucose Monitors LCD, the DME MACs present this proposed Glucose Monitors LCD following two separate reconsideration requests.

The first request, from a manufacturer, is to modify language in the LCD regarding the type of insulin allowed to be used in qualifying patients for continuous glucose monitors. The proposed LCD changes the language in criterion 3 from "insulin injections" to "insulin administrations," to allow the use of inhaled insulin preparations to meet the qualifying criteria for a CGM device.

The second request, also from a manufacturer, is to remove criterion 2, requiring that the beneficiary has been using a standard blood glucose monitor and testing supplies to perform frequent, as defined in the current LCD, as four or more times a day testing, prior to qualifying for a continuous glucose monitor.

The DME MAC Medical Directors have reviewed and noted that some of the presentations from scheduled presenters, presenters for today's meeting have comments, broad ranging, about the proposed Glucose Monitor LCD. We ask that in the interest of time you confine your public comments for today's meeting specifically on the proposed changes to the Glucose Monitors LCD. The Medical Directors appreciate that you may have comments about other criteria in the LCD and you're welcome to submit those comments in your written comments. However, today's open meeting is to solicit public feedback on the proposed LCD changes.

Stacie, we'll now open up the meeting for public comments.

Stacie McMichel *(6:00)***:** Thank you, Dr. Hoover. And as a reminder, please ensure that you have entered your audio PIN. Our first comments will come from Mahmood Kazemi with Abbott. Your line is now open, my apologies.

Mahmood Kazemi *(6:36)***:** OK, thank you very much now.

Stacie McMichel *(6:36)***:** And your time will start now.

Mahmood Kazemi *(6:38)***:** Thank you. Hello, my name is Mahmood Kazemi, and I am the divisional Vice President for Global Medical and Scientific Affairs, as well as the Chief Medical Officer at Abbott Diabetes Care. I have been with Abbott . . . I have been in the diabetes space for over 20 years.

As the Medical Directors are aware, Abbott Diabetes Care manufacturers, the Freestyle Libre line of therapeutic continuous glucose monitors, including the Freestyle Libre 14-day system and the Freestyle Libre 2. Both of these products have been confirmed by the Medicare PDAC as therapeutic CGM systems. We estimate that more than 130,000 Medicare beneficiaries rely on access to Freestyle Libre systems, and supplies, to manage their diabetes.

Moving to the summary slide, we're here to voice our strong support for the proposal to remove the requirement that a beneficiary self-test with a blood glucose monitor at least four times per day to qualify for Medicare coverage of the CGM system.

The proposed LCD reflects a good sample of the extensive, published peer reviewed evidence that confirms people with type 1 and type 2 diabetes, achieve improved outcomes with CGM use, regardless of how frequently they have been self-testing with a blood glucose monitor. We agree with the analysis of the evidence presented in the proposed LCD, as well as the conclusion that no evidence exists to support the four times per day requirement. In addition, as the proposed LCD recognizes, removing this restriction will better align the Medicare coverage criteria with clinical practice guidelines from the clinical associations most familiar with these patients and this technology, namely, the American Diabetes Association, the Endocrine Society, the American Association of Clinical Endocrinologists, and the American College of Endocrinology.

Especially during this continued pandemic, patient access to effective diabetes management tools is critically important to avoid serious COVID 19 complications that occur more frequently in people with poor glycemic control. We appreciate this important step forward in diabetes care, which will help clarify coverage for CGM systems, and we respectfully request that the proposal be finalized as soon as possible, to help facilitate patient access to this clinically important technology.

Thank you.

Stacie McMichel *(8:46)*: Thank you. Our next commenter, presenter will be from Janet McGill. And Janet, give me just a second, I'm unmuting your line. Good morning, Janet, your line is unmuted.

Janet McGill *(9:08)*: OK, thank you. OK, thank you very much for holding this forum, and I want to thank you for the opportunity to speak today. Before going on, I want to say that I fully support both proposals that insulin injection be changed to insulin administration which would encompass inhaled insulin, but also insulin pumps, in a way. And to remove the four times per day testing requirement. I would like to remind CMS and everyone listening, how important CGM is for safety. So the old adage of we'll prevent hypoglycemia by raising the A1C does not turn out to be true and has not worked and leaves our patients open for significant hyperglycemia. They take insulin and then they have a low. The WISDM study, clearly demonstrated that use of CGM in patients who are older, in the Medicare age range, mean age 68, reduced time below 70 milligrams per deciliter from 73 minutes per day to 39 minutes per day did not change in the blood glucose monitoring group. It's also important to know that much of these hypo events occur at night, when the patient is not testing their blood sugar with a finger stick. And the finger stick criteria do not pertain to those between testing opportunities where the patient is at risk for low blood sugar. Low blood sugar can lead to cardiac arrhythmias and they are absolutely certain that it leads to death. So I would encourage CMS to remove the four times per day, testing requirement so that we can utilize CGMs... with safety.

Stacie McMichel *(11:28)*: Thank you, Janet. I am sorry to interrupt but thank you for your comments.

Janet McGill *(11:32)*: Thank you.

Stacie McMichel *(11:35)*: Our next comments will come from Brett Carroll. Give me just a second to unmute your line. And we'll move on, I don't see that Brett has joined the call, so the next speaker will be Zoe Heineman. I'm unmuting your line.

Zoe Heineman *(12:29)*: Thank you. Good morning.

Stacie McMichel *(12:31)*: Thank you. Good morning.

Zoe Heineman *(12:33)*: Thank you, my name is Zoe Heineman. I am here today representing Diabeloop, a developer of algorithms and software solutions, for interoperable automated glucose controllers using alternative control enabled insulin pumps and integrated continuous glucose monitors.

I'm the Senior Vice President for North America. I am also a future Medicare beneficiary, as I am a patient with insulin dependent diabetes for 30 years.

I've continuously relied on insulin pump therapy, since 1992, and continuous glucose monitoring without calibration currently required, since it became available, to keep my blood glucose level as close to normal as possible.

Automated insulin delivery, relying on machine learning, connects external pumps with CGMs, in order to optimize an individual's time in target glucose range, thereby lowering the risk of severe hypoglycemia and long-term complications of diabetes.

There are some pumps with first generation invented algorithms, but not all pumps have this capability. Some systems are already being used by thousands of patients like me. Some of these systems are FDA approved, but some are not approved and were developed by patients as DIY, or otherwise known as we are not waiting community.

Diabeloop's products are developed with the goal of making patient choice a priority so that health care teams and patients can use the best combination of medical devices that best suits the individual's needs. I encourage everyone here today to act proactively to provide a pathway of coverage, either through pharmacy benefit, or through durable medical equipment benefit, for technological advances, so that there is no interruption in treatment that improves clinical outcomes. Specifically, prevent any interruption of CGM benefits and ensure that all three components of the closed loop system are covered, the CGM, the insulin pump, and the software to enable it. Thank you very much.

Stacie McMichel *(14:31)*: Thank you. Our next comment will come from Tim Trysla. OK, Tim, I see that your audio PIN has not been entered. For the sake of time, I've sent the audio PIN back to you, and we'll give you a minute to enter your audio PIN or move on to the next speaker. OK, I'll check again.

We'll move on to David Price with Dexcom. David, give me just a minute to unmute your line. Your line is unmuted. Good morning, David. David, can you hear us?

David Price *(15:53)*: Yes. Could you hear me now?

Stacie McMichel *(15:55)*: I can, thank you. OK, your time starts now.

David Price *(16:02)*: Yes, I'd, I'd like to thank the meeting organizers for the opportunity to comment on the suggested changes. Many, most of my slides, many of my slides are related to the overall coverage policy. But, so we don't really don't, I'll stick to the first slide only. So let's move on to the first slide.

So my name is David Price. I am Vice President of medical affairs at Dexcom, and my background is that of a diabetologist, who is both in clinical practice and, before I moved on to, to industry. So Dexcom supports the proposed changes.

There's a, we've presented extensive written comments that are well referenced about the overall policy, but in terms of these proposed changes I think we offer strong support.

The evidence supports the removal of the requirement for finger sticks prior to CGM therapy. There is evidence that the number of finger sticks used prior to initiating CGM has no impact on CGM, on the outcomes of CGM therapy.

We also believe that CGM benefits patients using insulin, whether it is injected, whether it is inhaled, or whether it is infused. If infused, it would be.. benefits would be realized, whether the pump is Medicare approved or not.

So thank you for the ability to comment on these. Once again, Dexcom offers strong support for the, the recommendations.

Stacie McMichel *(17:50)*: Thank you, David. OK, we'll move on to the next. My apologies, just a second here, we have to get through the slides.

OK, our next speaker will be Dean Millian. Give me just a second to unmute your line, Dean. Dean, I see here, also, that you have not entered your audio PIN. I've sent that to you.

And we'll move on to the next speaker and I'll circle back around to you, Dean, to see if your audio PIN is entered. But our next speaker is Jeff Farkas. OK, Jeff, I'm unmuting your line. Good morning, Jeff.

Jeff Farkas *(18:59)*: Very good. Good morning. My name is Jeff Farkas and I am Vice President for Health Economics, Reimbursement, and Government Affairs at Medtronic Diabetes. I appreciate the opportunity to present today. Next slide, please. Our first comment is that we support the two revisions proposed by the DMACs in the Glucose Monitor LCD. Next slide, please.

Our second and key comment is to call out the DMEPOS proposed rule issued by CMS in October, which proposes very positive changes to the Medicare benefit classification of CGM systems. Most notably, the proposed rule would classify all CGMs as DME which will have the effect of extending Medicare coverage to adjunctive CGMs. Medtronic is extremely pleased with this policy, and we thank CMS for the proposed rule.

In anticipation of a final rule, DMAC actions will be needed to implement the new policy, and the opening of this LCD provides an opportunity to do so. Next slide, please.

The key areas in which DMAC actions will be necessary are coverage and coding. With respect to coverage, the Glucose Monitors LCD will need to be updated to reflect and incorporate non adjunctive and adjunctive terminology proposed by CMS in the rule. This terminology may replace the current therapeutic language now included in the LCD.

With respect to coding, the DMACs will need to issue a clarified coding for CGM devices and update the associated Policy Article to bring it in line with CGM classifications established in the proposed rule. Clarification will also be needed with respect to any PDAC review and verification requirements pursuant to the rule.

The proposed rule included an effective date of April 1, this year. So, the changes to coverage and coding noted above will be needed in a timely fashion.

Our review of the Program Integrity Manual suggests that the DMACs have the flexibility and discretion to implement these changes in line, with the effective date in the proposed rule, consistent with the authority for MACs to implement changes about the Federal Regulation.

We will make formal written submission to the DMACs, but in the meantime, we appreciate your consideration to these comments and we encourage the DMACs to move expeditiously on these topics from the proposed rule. Thank you.

Stacie McMichel *(21:08)*: Thank you, Jeff. And our next comments will come from George Huntley. Good morning, George. Your line is unmuted.

George Huntley *(21:32)*: Thank you. Good morning and thank you for the opportunity to speak today. My name is George Huntley, I am a patient living with type 1 for over 37 years. I have three other family members, also with type 1, a sister on Medicare, I'm just a few years out. All four of us are currently using CGMs. I am also the current, currently the CEO of the Diabetes Leadership Council, and the Diabetes Patient Advocacy Coalition. We speak in favor of the changes that CMS has proposed in this regard with regarding to eliminating the finger sticks four more times a day, administering insulin three or more times a day, and removing the requirement of making frequent insulin adjustments.

CMS, CGM technologies is really life changing, game changing. It provides the full graphs connecting all the dots of your blood glucose, and it's essential to the patient regardless of how frequently they're currently pricking their fingers. In fact, the patient who's afraid to prick their fingers will benefit the most from this technology by getting more information. CGM should not be a reward for those who are compliant, it's a tool that is needed for those who are struggling. In addition, a patient already on a CGM like myself who turns 65, shouldn't have to go back to finger stick, sticks, to get Medicare coverage for a therapy that's already working.

Any patient on insulin can benefit from the information provided by CGM and the frequency and the manner of administration of the insulin is not relevant. A type 2 patient who administers long term, long acting insulin will benefit from CGM regardless if they're taking it multiple times a day, whether they are inhaling it or using a patch, it doesn't matter. So anyone on insulin or with extreme hypoglycemia or kidney disease will benefit significantly from a CGMs.

We also urge the inclusion of telehealth visits to qualify for the criteria of having met a healthcare provider prior to having, being… being prescribed the CGM. Telehealth is really important during this pandemic and it's the number one reason a senior citizen has missed an appointment. For… even prior to the pandemic was lack of transportation. So include telehealth as a qualifying meeting with your healthcare provider. And also…

Stacie McMichel *(23:45)*: Thank you for your comments.

George Huntley *(23:46)*: Thank you.

Stacie McMichel *(23:47)*: Thank you. We appreciate it.

George Huntley *(23:51)*: Yep.

Stacie McMichel *(23:56)*: We'll move on to the next speaker, and that will be Dr. Anne Peters. Let me unmute your line, Dr. Peters. Good morning, Dr. Peters, your line is unmuted.

Anne Peters *(24:17)*: Thank you. Next slide. Next slide. Hi. I'm Dr. Anne Peters and I support the proposed changes. I have two key points. First, I think it's been wrong to make seniors do something so hard, meaning finger stick glucose monitoring, to prove they need something so simple, meaning CGM. Second, the current rule worsens healthcare disparities because almost none of my underserved patients have the time or capacity to test and record their finger stick glucose levels four times a day. This deprives my less educated, poorer, patients from having access to CGM. Next slide.

I am going to let Doris make my point. Doris is a nurse in her eighties, with a long history of type 1 diabetes, and recently developed Parkinson's disease.

Now, this may be slightly jolty. Can you make it run? Well, if this worked, there she is. She's showing you how easy it is to see her glucose level on her on her iPhone. So, if you can swipe or look at your phone to see what your glucose level is, it's infinitely easier than what she's about to try to do. And the remainder of this video is of Doris struggling to do a finger stick. And if you could see it, you would see how tough it is for her to do this. So what I really believe is that seniors need access to CGM, which allows them to easily swipe a sensor or tap on a smart phone to see their glucose levels, rather than having to struggle through what you can't see, but could see, Doris do in order to get a finger stick glucose level to manage their diabetes. Thank you.

Stacie McMichel *(26:14)*: Thank you. Our next speaker will be Linda Langiotti. Give me just a second, Linda, and I will unmute your line. Good morning, Linda, your line is unmuted.

Linda Langiotti *(26:52)*: Thank you. Can you hear me?

Stacie McMichel *(26:54)*: Yes.

Linda Langiotti *(26:56)*: Great. Thank you. Good morning, everyone. Thank you for giving us the opportunity to make comments on the proposed changes. Many of you all know CCS Medical is the largest Medicare distributor of insulin pumps. And we're one of the largest providers of CGM in the nation. We service approximately 60,000 Medicare beneficiaries with diabetes. So we want to first take a moment to thank the DME MACs for that proactive review of the CGM policy and echo the earlier comments by many that we agree with the elimination of removing the blood glucose testing requirement of four times a day or more, as well as modifying criteria three from insulin injection to insulin administration.

We are the front-line servicing beneficiaries every day and both of these two issues have been significant barriers to beneficiary access and delayed start of CGM therapies, unnecessarily, due to the technical requirements of this criteria. So, we do, again, support the change and thank the DME MACs for making it.

In addition, while we're looking at criterion three, we do recommend that the, that the DME MACs consider changing the word Medicare insulin pump to just insulin infusion pump. At this time, Part D insulin pumps are not recognized as this policy to be administration of insulin of four times a day or more, even though these pumps are covered by Part D, and do deliver basal and bolus insulin, and we believe it's unnecessarily delaying therapy for beneficiaries and creating unnecessary paperwork burden. So, as you look at the criteria, if you, the one-word change can make a significant difference. Thank you.

Stacie McMichel *(28:38)*: Thank you. OK, our next comments will come from Cathleen Mullarkey. Give me just a second, and I'll unmute your line. OK, I'm not showing that Cathleen has joined our call, so we'll move on to the next speaker, and that will be Michael Sokol. Good morning, Michael. Your line is unmuted.

Michael Sokol *(29:59)*: Can you hear me?

Stacie McMichel *(30:00)*: Can you…Yes, we can hear you now.

Michael Sokol *(30:01)*: OK, cool, glad to hear it. I want to thank the CMS committee and Dr. Hoover for providing this opportunity to me. I am a practicing endocrinologist in Overland Park Kansas and have been practicing in this area for 27 years. Before that, I was 4 years, I had 4 years, in the United States Army as an endocrinologist as well.

My comments are directed towards the second portion of the change, that are recommended with regards to administration of insulin rather than injection of insulin. My concerns are with regards to inhaled insulin. I find that this is extremely helpful for my patients who are of Medicare age. In fact, I am seeing a patient this afternoon who is unable to afford inhaled insulin and is having repeated episodes of hypoglycemia. This is a major concern in the Medicare population. Inhaled insulin, has a, has the quickest onset of all insulins and has the shortest half-life of all insulins therefore reducing the episodes of hypoglycemia.

I believe that this provides a wonderful opportunity and benefit for our patients who are of Medicare age, who need control of their blood sugars following meals. The patient, for example, that I'm seeing afternoon, who could not afford inhaled insulin because she is on Medicare only continues to have to have episodes of hypoglycemia because she is required, because all that she could afford is injectable insulin at this time. That's the essence of my comments and I appreciate you giving me yield to these concerns to a person such as myself who is out in the field seeing 20+ patients everyday, many of whom are diabetic.

Stacie McMichel *(32:10)*: Thank you, Michael.

Michael Sokol *(32:13)*: You're welcome.

Stacie McMichel *(32:19)*: OK, our next comments will come from Claudia Enriquez. Good morning, Claudia, your line is unmuted.

Claudia Enriquez *(32:38)*: Yes, good morning. Can you hear me OK?

Stacie McMichel *(32:41)*: Yes, we can.

Claudia Enriquez *(32:43)*: Good morning. Thank you to the committee for having me this morning. I certainly appreciate you all allowing me to speak this morning. I am a practice, I am a practicing nurse practitioner in the state of New Mexico and I currently have a huge population of patients taking Afrezza that are also on CGM, and we want both of these to be approved together. We also want Afrezza to be part or offered under the $35 Medicare program. Afrezza is an ultra-rapid inhaling insulin of choice for the VDEX Clinic and my choice as well.

Afrezza is a nontraditional exhaust medication that has proven to lower blood glucose for every individual. It has some substantial benefits that I think that our diabetic community would benefit from adding this to the to this Medicare formulary. Thank you.

Stacie McMichel *(33:50)*: Thank you, Claudia. Our next speaker will be Paul Madden. Good morning, Paul, your, your line is unmuted. It looks like yourself muted, Paul.

OK, we'll move on to the next speaker, and then we'll circle back around to you, Paul, but you will need to take yourself off of mute. Our next speaker will be Michael Castagna. Good morning, Michael. Your line is unmuted.

Michael Castagna *(35:24)*: Thank you. Good morning, everyone, and thank you for opening up this opportunity to consider adding inhaled insulin coverage to the criteria for CGM. My name is Michael Castagna, and I'm a clinical pharmacist and CEO of Mannkind Corporation.

We have studied inhaled insulin in almost 70 trials, invested over $2 billion over the last 30 years to create the differentiating mealtime insulin that serves an unmet medical need as you've heard today. Our founder, Alfred E. Mann, knew 20 years ago, before we had CGM that people struggle managing their diabetes, because of the slow acting nature of injectable insulin causing people to have low and high blood sugars.

Fast forward to 2021, we've seen minimal improvement in the time action profile of injectable insulin, and outside of inhaled insulin, most of the innovation for meal-time control has been on the technology side, especially CGM and automated pumps.

As you'll hear from Dr. Kaiserman, the data we have generated using CGM and inhaled insulin, has demonstrated that these two tools, when used together, can greatly improve patient outcomes, over what we are paying for today.

Our elderly population, living with diabetes, are more susceptible to falls, which can lead to hip fractures as well as hospitalization, due to hyper and hypoglycemia. We believe inhaled insulin can help reduce these types of risks, especially when used with CGM because it's in the blood in seconds and starts to work in minutes.

One of our recent studies in older patients using inhaled insulin, and using Libre as a CGM, demonstrate over 90% of patients lowered the A1C to less than 8% in 12 weeks, without the increased risk of severe hypoglycemia, which can be life-threatening. Please consider making inhaled insulin an equal alternative to injectable insulin for Medicare patients trying to access CGM.

I hope we can continue the open dialogue around affordable access in 2022 for inhaled insulin, as the rebate game for PBMs drives up the cost of our insulin, as you've already heard, for Medicare beneficiaries who deserve access to all formulations of insulin, available to them, to achieve adequate control.

Thank you again for this consideration.

Stacie McMichel *(37:21)*: Thank you, Michael. Our next speaker will be Kevin Kaiserman. Give me just a second to unmute your line. OK, good morning, Kevin. Your line is unmuted.

Kevin Kaiserman *(37:51)*: Good morning and thank you for the opportunity to speak today. My name is Dr. Kevin Kaiserman and I am a pediatric endocrinologist who recently joined Mannkind Corporation as their Vice President of Medical Affairs and Safety.

Over the past few years, Mannkind has conducted several studies with CGM and type 1 and type 2 diabetes patients. All showing improved outcomes. Two studies are particularly relevant to today's discussion as the subjects were close in age to the Medicare population.

The first study I will highlight is Levin et al. with an average subject age of 61 years. This study added inhaled insulin to insulin naive patients, demonstrating a 1.6% reduction in A1C over 12 weeks. The time in range increased by an average of 6.5 hours per day with no severe hypoglycemia reported.

The second study, Kipnes et. al with an average subject age of 65 years, took patients who are relatively stable and switched them from injectable insulin to inhaled insulin and added CGM. This study demonstrated an A1C improvement of 0.8% in inhaled insulin treated group over 14 weeks with no increase in hypoglycemia. Reducing hypoglycemia, which often disrupts an individual's balance, is especially important for our seniors that have higher risks for more serious injury and increased medical expense with falls. As a physician, treating patients with diabetes over the past 25 years, I've had the privilege of offering several new therapies as they have come to market to assist people in managing their condition with less burden, increased safety, and reduced long-term risk.

I am specifically requesting that clinicians and patients be allowed to have flexibility and freedom in their choice of which diabetes therapeutics work best for each individual patient and situation. I've worked with CGM since the beginning, and I've seen firsthand the empowerment that the increased information provided by CGM has provided the patients and their loved ones

to assist them in a difficult management of their chronic disease. Please consider adjusting the CGM PA criteria to allow for the use of inhaled insulin, Afrezza, which more closely mimics physiologic insulin secretion with an ultra-rapid onset of action and clearance, which may reduce the risk for hypoglycemia. Monitoring of the glucose values with CGM allows patients to closely observe the effects of their insulin dose on food, high glucose corrections, and the day-to-day variability of living with diabetes. Thank you for your consideration.

Stacie McMichel *(39:58)*: Thank you, Dr. Kaiserman. OK, and I'm going to go back around to the presenters that had a little bit of technical difficulties. Tim Trysla, I see that your PIN is now entered. I'm going to unmute your line. Good morning, Tim, your line is unmuted.

Tim Trysla *(40:20)*: Good morning, Stacie. Thank you, Stacie. Can you hear me?

Stacie McMichel *(40:24)*: Yes, we can hear you.

Tim Trysla *(40:26)*: OK, great. Thank you so much to all the, for C…for CMS for convening today's call. My name is Tim Trysla, I am the Executive Director of the Diabetes Technology Access Coalition, the DTAC. Thank you for the opportunity to provide these comments and proposing these much needed changes to coverage of continuous glucose monitors.

The DTAC was founded by major manufacturers of diabetes equipment, technology, including CGMs. Our purpose is to represent the unified diabetes community voice through our close collaboration with major diabetes patient groups, advocacy societies, and physician societies. We have heard from CMS and Congress, that a unified stakeholder voice is essential to improving coverage and access, and we aim to fill that role.

CGM is a transformational technology. As you will see in our submitted comment letter, the value of CGM is well documented, helping patients to effectively control their diabetes, prevent adverse outcomes, such as unnecessary hospitalizations and emergency department visits, and save the federal government millions of dollars by avoiding unnecessary healthcare utilization. In other words, CGM represents a high value solution to diabetes, which affects millions of Americans. Currently, there are many unnecessary barriers and administrative burdens that are inappropriately limit beneficiary access to CGMs.

We strongly support the proposed changes, including the removal of the four or more times daily finger stick requirement, as well as changing the terminology from insulin injections to insulin administrations. These are important changes but are needed to, that are needed to, ensure beneficiaries have access to these lifesaving technologies. Notably, we urge for a reshaping of the approach to diabetes technology coverage to one that is founded in clinical evidence, and that does not create barriers to care.

Thank you again, and we look forward to the continued engagement on this critical issue.

Stacie McMichel *(42:16)*: Thank you, Tim. And our next presenter is Dean Millian. I see that your PIN is entered. I'm going to unmute your line, Dean. Give me just a second here. Good morning, Dean, your line is unmuted.

Dean Millian *(42:39)*: Good morning, Stacie. Byram Healthcare would like to thank everybody for the opportunity to provide some comments.

We support the proposed changes around eliminating the requirement that Medicare beneficiaries demonstrate the use of more than four finger sticks per day to qualify for CGM coverage, and the use of the word administration instead of injection, to allow inhaled insulin.

We would also like to see the requirement around the insulin being tested three times a day, as well as what the word frequent means around adjusting insulin. Frequent is a very vague term, and it makes it very difficult to administer the policy, using that word. We'd like further clarification on that, because this all ties back to the finger stick. Thank you for your consideration.

Stacie McMichel *(43:28)*: Thank you, Dean, and our last presenter will be Paul Madden. Paul, I'm going to unmute your line here in just a second. Good morning, Paul, your line is unmuted.

Paul Madden *(43:46)*: Thank you very much. Can you hear me? Can you hear me?

Dr. Robert Hoover *(43:56)*: Yes, we can hear you.

Stacie McMichel *(44:01)*: Paul, are you there?

Paul Madden *(44:10)*: Can folks hear me?

Stacie McMichel *(44:12)*: We can now, yes.

Paul Madden *(44:14)*: OK, sorry. Another person said they could hear me, when you couldn't hear me, sorry. All right, I am living a healthy life that has included insulin dependent diabetes for 59 plus years, supported by family and access to optimal diabetes medicines

and technologies, as agreed to with my diabetes teams. I've also been a diabetes educator, counselor, psychologist, and advocate for 44 years, 30 years with the Joslin Clinic.

First, I want to thank you for your wise investment in healthier lives of us seniors living with diabetes by including CGMs in Medicare coverage. I've been using CGMs for 15 plus years, and your decision allows me to continue to benefit with my Medicare coverage.

My second thought is to encourage the continued review and approval of medicines and technologies that help … seniors maintain more normal blood sugars and stay safe to realize healthier, more robust lives.

Prior to beginning Medicare coverage, I was using the unique ultra-fast acting Afrezza, orally, inhaled insulin with my basal insulin and CGM. This combination allowed me to stay in normal blood sugar range, on average 90-95% of the time, with rare blood sugar extremes. With no Medicare coverage, I'm discouraged and less well balanced with my diabetes, working harder to be in that normal blood sugar range, just 80-85% of the time, with more extreme and low blood sugars, which are disruptive and less safe for me as a senior.

Two of the key, more important Afrezza benefits that I and other seniors realize are blood sugars in target range more often and our increased safety with the reduction of these extreme blood sugars. I, along with a growing number of patients and healthcare professionals, are inviting you to include insulin to the coverage, inhaled insulin to coverage criteria for CGM, and we invite you to address and approve Medicare coverage for Medicare recipients to grow their healthy and quality of life success, that I and others are realizing, and that are demonstrated by the studies.

Medicare coverage of Afrezza is a wise investment for seniors to improve the health and lives of people living with diabetes.

Thank you so much.

Stacie McMichel *(46:36)*: Thank you, Paul. Thank you and this concludes our comment period for the first policy. I'll go ahead and turn it back over to Dr. Hoover for closing remarks.

Dr. Robert Hoover *(46:50)*: Thanks, Stacie and thanks to our commenters today. I'd now like to discuss the LCD reconsideration process and next steps. On your screen, you will see the information about how to submit comments on the proposed Glucose Monitor LCD and the closing date for the comments. Once the comment period closes the DME MACs will consider today's comments and the information presented. We'll also be considering comments received in writing from stakeholders. Once comments are considered and collated, we'll review the proposed LCD language and make any changes necessary as a result of the comments received.

We'll also do any additional research and then post a final LCD, along with a Response to Comments document. The DME MACs will post our final LCD on our websites and distribute links to the information via our ListServs. The final LCD will take effect a minimum of 45 days following the posting of the final LCD.

Thank you for attending today. This portion of the meeting is adjourned. For those registered to provide public comments on the External Infusion Pump proposed LCD, I'll turn the meeting over to Dr. Ballyamanda and we'll begin shortly. Stacie, do we have Dr. Ballyamanda's line unmuted?

Dr. Smitha Ballyamanda *(49:12)*: OK, let me, can everybody hear me?

Stacie McMichel *(49:17)*: Yes, we can hear you.

Dr. Smitha Ballyamanda *(49:19)*: OK, Good morning, everybody. Good morning and welcome to our virtual meeting. This meeting is regarding the External Infusion Pumps Local Coverage Determination. My name is Dr. Smitha Ballyamanda, the Jurisdiction A DME Medical Director. I work for Noridian Healthcare Solutions and with me today, also from Noridian Healthcare Solutions, is Dr. Peter Gurk with Jurisdiction D and from CGS, is Dr. Stacey Brennan from Jurisdiction B and Dr. Robert Hoover from Jurisdiction C. We're looking forward to hearing your comments regarding the External Infusion Pump LCD. Please put these comments in writing and send them to us via e-mail at EIPrecon@Noridian.com. Again that's E, I, P, R, E, C, O, N at Noridian N, O, R, I, D, I, A, N dot com.

Details for submitting comments are also available on the DME MAC websites. Please remember that we can only respond to the written comments. These comments are due by the close of business on Saturday, January 30th, 2021. Also, we will be recording the meeting today which will be posted on the DME MAC websites. You are giving your consent to use the use of your recorded voice and comments by signing into the meeting. Please be careful about sharing any personal health information in your verbal comments.

We have five commenters who have pre-registered to speak. We're only permitted, permitting registered commenters to speak at today's meeting, but anyone can submit written comments to the e-mail address I mentioned earlier. For those pre-registered commenters, each person will have five minutes to speak. For those on the phone who are listening, again, please mute your phone line and computer.

And, again, we ask that you do not place this call on hold, because we will all be forced to listen to background music. Speakers should be prepared to begin their comments immediately after called upon. Now, I turn it back over to our moderator Stacie.

Stacie McMichel *(51:48)*: Thank you and just as a reminder, please make sure that you have entered your audio PIN into your telephone keypad. The audio pane is located in the upper right-hand side of the GoToWebinar portal. If you can hear me but have not entered your audio PIN, please be sure to hit pound, the audio PIN, and pound again. This is imperative to do so that we can unmute your line so that you can speak.

Note that we are experiencing technical difficulties with the opening meeting CGS e-mail address. If you are having any difficulties with meeting access, you may e-mail us directly at LCDreconJC@CGSadmin.com for support.

We will now go to our first speaker and that will be Zoe Heineman. Zoe, I'm going to unmute your line. Good morning, Zoe.

Zoe Heineman *(52:51)*: Good morning. I had already shared my comments previously. Is, is it? Did you want me to repeat my comments or? Because I thought I was only given one opportunity to speak. Hello?

Stacie McMichel *(53:12)*: Yes.

Zoe Heineman *(53:12)*: Can you hear me?

Stacie McMichel *(53:13)*: We are here.

Zoe Heineman *(53:14)*: OK, so I already shared my comments. If you'd like me to repeat them, I can.

Stacie McMichel *(53:22)*: Medical Directors, are we okay to move on?

Dr. Robert Hoover *(53:25)*: Yeah, this is Dr. Hoover. We've moved to a second proposed LCD. If your comments were related to the Glucose Monitors LCD, we already have those and you're welcome to drop off and not provide the same comments for a different policy.

Dr. Smitha Ballyamanda *(53:49)*: Hello, this is Dr. Ballyamanda, again. I apologize. I actually wanted to give a bit of an overview about the EIP, and maybe that will help mitigate this. I just wanted to take a few minutes to discuss the proposed policy, again. Stacie, is that OK?

Stacie McMichel *(54:05)*: Perfect. Yes, thank you.

Dr. Smitha Ballyamanda *(54:08)*: Sure, apologize once again. Just a little overview of the proposed EIP LCD, this provides coverage for Hizentra, which is an immune globulin subcutaneous solution. This is manufactured by CSL Behring and Company. This drug was approved by the Food and Drug Administration on March 15th, 2018, and is assigned the injection immunoglobulin HCPCS Code of J1559. The proposed external infusion pump language, posted on December 17th, 2020, will add coverage language for this drug. It is administered subcutaneously via an external infusion pump to the Medicare beneficiary, within the home, for the treatment of chronic inflammatory demyelinating polyneuropathy. Again, I apologize for not stating that in my introduction, and hopefully this makes things clear, as far as which policy we are now discussing.

And if you are not here to make any comments regarding the EIP policy, please feel free to drop off. Thanks. Back to you, Stacie.

Stacie McMichel *(55:16)*: Thank you. OK, our next speaker would be Linda Langiotti. Just a second, and I'll unmute your line. Good morning, Linda. Your line is unmuted.

Linda Langiotti *(55:37)*: Thank you very much. Thank you, everybody. I do realize that the opening of the External Insulin Pump policy, I'm sorry, this is Linda Langiotti, CCS Medical. We're the largest distributor of Medicare insulin pumps in the nation.

So, I wanted to take an opportunity, while you all were considering the External Infusion Pump policy, just to point out a few inconsistencies between policies that creates a lot of barriers to access, beneficiary and healthcare professional confusion in the marketplace, and I just respectfully ask that maybe the medical directors can review this in context of the changes being made to the glucose value, excuse me, the Glucose Monitor policy. Because the reality is, patients can be on the glucose monitor and an external infusion pumps.

So, the two policies have some disconnects. Specifically, I ask that the consideration that you're making in the blood glucose monitor for CGM policy, for the administration of insulin be considered for the insulin pump policy. Today, the insulin policy pump policy requires a beneficiary to inject insulin for six months prior to the initiation of the insulin pump. It is our reality every day, that we see people on inhaled insulin that transition to injectable insulin and they can't meet the six month criteria of injecting insulin, but clearly meet a six month criteria of administration of insulin, with frequent self-adjustment.

So if that change is made to the CGM policy, perhaps it should be made to the external insulin pump section of the policy, which is criteria IV.C. In addition, criteria IV.C. requires the beneficiary to test four times a day or more, for two months prior to the initiation of an insulin pump. But we are discussing removing that criteria from the initiation of a CGM.

So, there's a couple comments. For anyone utilizing insulin to live, if you're not making frequent self-adjustments and with some sort of blood glucose value, you really can't inject your insulin. But for beneficiaries on non-therapeutic CGM, or beneficiaries still using blood glucose monitors, they have a market access challenge trying to get four times a day testing, because the Glucose Monitor policy says normal usage for insulin treating is three times a day and high utilization is four or more.

And many diabetes testing supply providers won't provide four or more because they don't want to deal with the claims burden, and for the beneficiary, they can't get the four or more covered by their benefits due to the claims challenge the providers face. And many doctors said they believe Medicare only covers three times a day testing because of the normal utilization guidelines in the glucose policy.

So, there's just a disconnect between those policies that should be considered for review and to remove more barriers to access for beneficiaries.

Lastly, for patients that become Medicare eligible from the commercial and Medicaid environment, the testing requirement of four times a day, the month prior to eligibility, same logic applies, it could be on a non-therapeutic CGM, they may have different requirements in their commercial environment for testing requirements. So that puts an unnecessary burden on them. And I would also encourage the acknowledgement of Part D covered Omnipod system as an insulin pump.

In the commercial and Medicaid markets, an Omnipod is covered by their external infusion pump policy. It is viewed as an insulin pump. So, when patients become Medicare Medicare eligible on an Omnipod, Medicare does not view that as coming into the system on a pump and does not make it easy to transition to the Part B covered item. And those create unnecessary barriers for our beneficiaries for access and delay of therapy. So, from my perspective, for those of us who work on the frontline to service beneficiaries every day, I just think you should consider that the diabetes community is working through both these policies, and maybe looking at aligning them makes more sense from a beneficiary access, paperwork burden, and for the community as a whole.

Thank you for your consideration.

Stacie McMichel *(1:00:08)*: Thank you, Linda. Our next speaker will be Kimberly Weiss. And I'm, I don't see that Kimberly has joined our call. So we'll move on to our next speaker, Bill Noyes. Give me just a second to unmute your line. Good morning, Bill. It looks like you're self-muted, if you can unmute. There we go.

Bill Noyes *(1:00:53)*: Hi Stacie.

Stacie McMichel *(1:00:54)*: Good morning. Hello.

Bill Noyes *(1:01:01)*: Hi Stacie. Can you hear me?

Stacie McMichel *(1:01:03)*: I can, I can hear you.

Bill Noyes *(1:01:04)*: Okay, great.

Stacie McMichel *(1:01:05)*: Good morning.

Bill Noyes*(1:01:06)*: My name is Bill Noyes. I'm the Senior Vice President of Reimbursement Policy for the National Home Infusion Association, and I appreciate the opportunity to provide comment in this virtual public forum on behalf of the Association.

The National Home Infusion Association, NHIA is a trade association representing home infusion therapy providers, suppliers, equipment manufacturers, distributors, drug manufacturers, and other industry stakeholders.

My comments today are limited to the proposed modifications to the External Infusion Pumps LCD, adding coverage of Hizentra for the indication of CIDP.

NHIA has reviewed the proposed External Infusion Pump LCD, as well as the proposed Policy article, and would like to stress that coverage under the DME program should be limited to approved indications. And we believe that the proposed changes does just this, by limiting it to approved indications, in this case: G61.81 ICD-10 code.

We would like to voice a concern around shifting coverage of infused drugs from Part D as in dog to Part B, as in boy, which is exactly what this proposed change would do.

We understand that about 80% of Medicare beneficiaries have some type of supplemental coverage for their Part B, as in boy, out of pocket costs in the form of Medicaid, a retirement plan, or Medigap, leaving about 20% without supplemental coverage. If those that do not have supplica-supplemental coverage have a need for subQ Ig, their out of pocket cost in Part B would likely put their treatment out of reach. Under the DME program, the beneficiary is responsible for 20% of carbon, of charges. 20% of charges without a cap, it never caps. An example of an 80 kilogram beneficiary receiving a common dose of Hizentra, one gram per kilogram every three weeks, the beneficiary's co-pay, would be over $30,000 annually and that concludes my comments.

I thank you for your time and consideration.

Stacie McMichel *(1:03:40)*: Thank you, Bill. Our next comments will come from Dina Inverson. Inverso, excuse me. I'm going to unmute your line, Dina, in just a second. Alright, you're unmuted, good morning.

Dina Inverso *(1:04:01)*: Good morning, thank you. This is Dina Inverso, and I lead our reimbursement and patient engagement functions at CSL Behring. I want to thank the committee for allowing CSL Behring to make comments on the proposed changes to the External Infusion Pump Local Coverage Determination.

We agree with the proposed revisions. We specifically agree with the revisions in Section V., subsection H that adds criteria: 3 to 5 for Hizentra, J Code 1559, providing CIDP coverage. We strongly urge the DME MACs to finalize these changes in the External Infusion Pump Local Coverage Determination and also regarding the accompanying Local Coverage Article, we have two comments.

Regarding the statement on page 12, claims for Hizentra beneficiaries with CIDP for dates of service on or after March 15, 2018 must be submitted with HCPCS Code J1559. We interpret this statement to mean the coverage of Hizetnra for CIDP will be retroactive back to the FDA approval date for Hizentra with CIDP, which was March 15th we, of 2018, and we request that the DME MACs make this effective date clear in their finalized LCD.

And secondly, regarding Group 6 ICD-10 codes on page 32, to maintain continuity of care for beneficiaries aging into Medicare, we request that you add two ICD-10 codes which are routinely seen in commercial coverage policies for CIDP, and those ICD-10 codes are G61.89 and G61.9. We encourage that the LCD be implemented in an expedited fashion. No later than 4.1.21.

And we also wanted to thank the DME MACs' medical directors for the process and their efforts in revising and updating this LCD. Thank you kindly.

Stacie McMichel *(1:06:35)*: Thank you, Dina. At this time, this concludes our comment segment, and I will turn it back over to Dr. Ballyamanda for closing remarks.

Dr. Smitha Ballyamanda *(1:06:52)*: Thank you, Stacie. Just confirming, everyone can hear me, correct?

Stacie McMichel *(1:06:58)*: Yes, we can hear you.

Dr. Robert Hoover *(1:07:00)*: Yes.

Dr. Smitha Ballyamanda *(1:07:01)*: Thank you. We would like to thank all the members of the public and stakeholders for your thoughtful comments today. Once again, please remember to send your comments in writing. If you have any full text, peer reviewed articles, to help support your comments, that are not included in the bibliography, please send them along as well. As another reminder, the comment period will end on Saturday, January 30, 2021.

Once we have considered and collated all of the comments received during the open comment period, we'll consider any changes necessary as a result of the comments received and then post a final LCD along with a response to comments document. The final LCD will take effect a minimum of 45 days following the posting of the final LCD.

For any updates, please refer to the DME MAC websites. And I want to thank everyone again for their participation today. We will formally adjourn this meeting at this time.