Open Meeting: Glucose Monitors

Meeting Date & Time:	November 15, 2022, 10:00 a.m. ET
Facilitator:	Belinda Yandell
Location:	Virtual Meeting

Belinda Yandell (0:06): Good morning, everyone, my name is Belinda Yandell, I am the moderator for today, and it is 10 o'clock.

So, we are ready to get started. Doctor Hoover, I'll turn this over to you. Just let me know when you want slides advanced.

Dr. Robert Hoover (0:24): Thank you, Belinda.

Well good morning, everyone, and welcome to our Virtual Open Meeting.

Thank you to our registered speakers and attendees on the phone.

Today we'll solicit comments from the public regarding the proposed Glucose Monitors Local Coverage Determination or LCD. My name is Doctor Robert Hoover and I'm with CGS Administrators, the Jurisdiction C DME MAC. Also, from CGS is Doctor Sunil Lalla from Jurisdiction B.

Representing Noridian Healthcare Solutions are Doctors Smitha Ballyamanda and Angela Jenny with Jurisdictions A and D, respectively.

Moderating the phone lines and keeping our speakers on track is Belinda Yandell from Provider Outreach and Education at CGS.

Speakers, you'll take your cue to speak from her.

We look forward to hearing your comments regarding the Glucose Monitors LCD.

Please put these comments in writing and send them to us by e-mail at – and this will be all one word – GLULCDComments, that's G L U L C D comments at CGS admin dot com. Details for submitting comments are also available on the DME MAC websites.

Please remember that we can only respond to written comments and the comments are due by 5 PM Eastern this coming Saturday, November the 19th.

Also, we will be recording the meeting today which will be posted on the DME MAC websites.

You're giving your consent to the use of your recorded voice and comments by signing into this meeting.

As a reminder, please be careful about sharing any personal health information in your verbal comments.

We have 10 commenters who were pre-registered to speak.

We're only permitting registered commenters to speak at today's meeting, but anyone can submit written comments to the e-mail address I mentioned earlier.

For each speaker today, we ask that you introduce yourself, the organization that you represent, and disclose any conflicts of interest you may have with this topic.

For those listening on the phone, please mute your phone line and computer.

Do not, I repeat, do not place this call on hold, because we'll all be forced to listen to background music.

Speakers should be prepared to begin their comments immediately after called upon.

I'll now turn the presentation over to Doctor Sunil Lalla to go over the highlights of the proposed LCD.

Dr. Sunil Lalla (2:49): Thank you, Bob.

Before I provide the brief overview of the proposed Glucose Monitors LCD, I would like to take just a moment to recognize my predecessor, Doctor Stacey Brennan, who has announced her retirement, effective shortly after the first of the year. Doctor Brennan has been the former JB Medical Director and has served the Medicare Program for several decades.

This meeting is bittersweet, as this will be Doctor Brennan's last open meeting.

On behalf of CGS and all of the Medicare Administrative Contractors, I thank Doctor Brennan for her contributions and wish her much joy and happiness in the next chapter of life.

Now, a little bit about the proposed Glucose Monitors LCD. The DME MACs – in response to the reconsiderations – are proposing to modify the coverage criteria for CGM devices to allow reimbursement for this technology when the beneficiary is administering insulin one or more times per day.

This is different than the current requirement of insulin administrations three or more times per day.

The proposed LCD also expands coverage for beneficiaries, regardless of diabetes type or use of insulin, when their treatment regimen results in a history of problematic hypoglycemia and problem– problematic hypoglycemia is further defined in the proposed LCD.

The proposed LCD also clarifies the existing rules that allow an in-person evaluation requirement to be accomplished by a Medicare-approved method of telehealth.

I'll now turn the microphone back over to our moderator, Belinda Yandell from CGS. Belinda?

Belinda Yandell (4:42): Thank you, sir, as we get ready here, let me move our slides forward.

First comments today are from Stewart Perry.

Mister Perry, I'll turn it over to you.

Mister Stewart Perry, are you available? Seem to be having some issues here.

Stewart Perry (5:45): Here we go.

Belinda Yandell (5:46): There you are.

Stewart Perry (5:47): Yes, ma'am. We were muted by the moderator. We couldn't get ours to unmute.

Belinda Yandell (5:52): That's my apologies.

Stewart Perry (5:54): No problem. Thank you very much, forgetting the technical difficulties.

So, thank you, Directors Ballyamanda, Lalla, Hoover, and Jenny for the opportunity to comment on Glucose Monitors proposed Local Coverage Determination.

My name is Stewart Perry. I've been an advocate for people with diabetes for well over 30 years.

In fact, this year, I currently enrolled in Medicare myself. That tells you just how old I am.

I'm the co-founder and current board Chair of the Diabetes Leadership Council. Before founding the Diabetes Leadership Council, I was– I'm the past Chairman of the National Board of Directors of the American Diabetes Association, and I'm the past Chair of the National Advocacy Committee that I served for five years. In my real job, I own a State Farm Insurance Agency and have been licensed to sell health insurance in the Commonwealth of Kentucky for almost 40 years.

I became a patient advocate after I was diagnosed with type 2 diabetes more than 30 some years ago, but diabetes has been a family curse of mind for many generations.

I lost a son with type 1, a father, an uncle, a grandfather, and a great grandmother with type 2 diabetes. So, I grew up with this disease.

Between my family and my advocacy work, I've seen firsthand the difference it makes when a person with diabetes has access to the correct tools to manage their disease and when they don't have access to those tools.

Let me begin by applauding you for these incredibly important changes and for inviting dialogue, particularly from patients who rely on CGMs or continuous glucose monitors.

It paves the way for more affordable and equitable access.

It is life changing and lifesaving, but many times underutilized technology.

The Diabetes Leadership Council is a member of the Diabetes Technology Access Coalition, and other coalition members and clinician partners will share the coalition's strong support for these proposed LCD and recommendations for the final LCD.

Let me share my personal perspective on the importance of monitorizing and simplifying the Medicare's diabetes coverage, as a beneficiary who has diabetes, as someone who has cared for loved ones with diabetes, and as a professional who has counselled people on choosing and using health insurance. We need to prioritize what's best for patients and keep things simple.

I'd also like to underscore the urgency of finalizing this LCD before the COVID 19 public health emergency expires to avoid confusion and potentially dangerous disruptions in care.

Coverage certainly helps preserve continuity of care for patients using a CGM, and when they age into Medicare, for some existing– and some existing beneficiaries who would benefit from CGMs.

It will also provide relief to Medicare providers, allowing them the prescribed treatment based on clinical evidence and their patients' unique requirements, rather than Medicare's unique requirements.

While the proposed LCD is a vast improvement over the status quo, we have three suggestions to improve it.

First, align the CGM 30-day billing cycle with the insulin pump 90-day billing cycle. It makes no sense to receive 90 days of supplies and then to be told your billing is 30 days. If you get 90 days, you should be billed for 90 days. Let's keep it simple.

Aligning the billing cycle for CGM, for insulin pumps, and other covered technology and supplies would be a good step in simplifying.

Second, protect beneficiaries' access to all insulin options.

The insulin landscape is constantly changing and that's good for patients.

We don't need to come back at a later date and fix language that we could have gotten first– right the first time.

We need to make sure that Medicare beneficiaries using CGMs have access to the insulin that works for them once it's been approved by the proper channels, regardless of how it's administered and how frequent.

Therefore, we ask you revise the language in criterion 4A to state that beneficiaries treated with any insulin. Our recommendation is to keep this requirement as broad as possible to avoid restricting beneficiaries' access to the insulin they need now or in the future.

Third, clarify the FDA indications for use will not result in beneficiaries losing access to CGMs.

Diabetes is a disease that treats everybody differently. Your needs change over time and the set of tools you use change as well.

Again, we want to prioritize what's in the best interest of the patient and keep things simple for them.

The proposed LCD seems to allow Medicare beneficiaries to access and use CGM therapy, to manage their diabetes in line with the FDA's indication.

We're concerned that additional language is needed to protect beneficiaries if they develop a condition for which CGM is not specifically indicated. A strict reading may cause them to lose this coverage. A few examples, pregnancy and dialysis.

Ultimately, we believe the beneficiary and prescribing clinician should jointly make the determination as to whether CGM use is safe and medically appropriate.

We would ask you provide clarity that the original CGM prescription takes precedence over the condition for which CGM may not be intended or primarily intended. As I've shared with you, we believe that the LCD is a great step forward and makes meaningful improvements for Medicare beneficiaries who need access to CGM.

We truly appreciate the opportunity to comment and as you finalize this LCD, we really hope that you will take these comments into consideration.

Thank you for the opportunity to represent patients with diabetes at today's meetings. I appreciate it.

Aaron Turner-Phifer (12:39): Good morning. It looks like I'm unmuted here. Aaron Turner-Phifer, director of health policy at JDRF.

I just want to thank everyone this morning, to echo previous comments. I want to thank folks for the opportunity to provide comments today. It's so important I think that we have an opportunity on the patient community side to provide feedback and to these important changes.

So, JDRF's background is the world leading private funder of type 1 diabetes research. We were founded by two families whose children had type 1 and for 50 years JDRF has led efforts to find cures for this disease and invest in breakthrough innovation to improve the lives of those living with type 1 diabetes.

We want to thank you for the proposed LCD, as we believe it will remove unnecessary barriers to this vital technology and improve access for Medicare beneficiaries with diabetes.

We will provide detailed comments following this meeting, but broadly speaking, we are very supportive of the expansion of CGM access as proposed, as this brings Medicare policy more closely in line with ADA Standards of Care, which recommend CGM use for all people with diabetes.

We also strongly support the allowance of telehealth visits for initial and continuing coverage of CGM.

Many in our community have enjoyed the increased flexibility offered by telehealth visits and, especially through the COVID 19 pandemic, many folks who have been new since telehealth visits really have a desire to continue utilizing them into the future. So that flexibility continues to be important, moving forward.

We'll provide detailed comments in written form at the end of the week, but there are a few areas where we offer– we will offer recommendations to further enhance access to CGMs.

I want to highlight one issue of note that was also previously raised. Criteria 3 requires use of a CGM in accordance with the FDA indication. We're unaware of a similar precedent in utilizing– utilizing this language for CGM, or any other type of device that would potentially restrict access in this way. We'd encourage additional clarity for this specific requirement in order to avoid any confusion that may unduly restrict or delay access to CGM.

To close here and to wrap up, of the approximately one point four million Americans living with type 1 diabetes today, CGMs have become an essential and vital tool in the management of their diabetes.

From inception to publication of the seminal research demonstrating the positive impact of CGMs on health outcomes, JDRF and the type 1 community have been strong champions for the role of the technology to improve the lives of those living with diabetes.

We've certainly come a long way in CGM coverage. A little more than a decade ago, many payers, including Medicare, questioned the utility of such a device to improve health outcomes. And today, CGMs are the standard of care for people with both type 1 and type 2 diabetes and CGMs are broadly covered by commercial insurers and Medicare. This proposed LCD rule would update and provide an important step forward in our progress to ensure everyone have timely access to this biotechnology. Again, we want to thank you for the proposed update, given the speed of innovation and diabetes technology we'll look forward to coverage criteria that keep pace with the technological advances and the clinical standards of care, and appreciate the opportunity to comment and thank everyone again.

Belinda Yandell (16:20): Thank you, sir. I appreciate your comments.

I'm putting you back on mute, and we move forward with Mahmood Kazemi.

And let me find you here and make sure I have unmuted your line.

[Inaudible]

Mahmood Kazemi (16:44): Good morning.

Belinda Yandell (16:45): Good morning.

Mahmood Kazemi (16:46): Excellent. Thank you so much.

Let me just, excellent. You have the slides for me as well. I believe we have some slides. I'm not sure. Ah, there we go. Excellent. Thank you so much.

Good morning. This is Mahmood Kazemi, I am the Chief Medical Officer for Abbott's Diabetes Care business. I'm an employee of Abbott and receive compensation in that role.

I'd like to thank the DME MAC Medical Directors for the opportunity to comment on the proposed modifications to CGM coverage criteria and the Glucose Monitors LCD referenced here.

If you could advance to the next slide, please. Perfect.

Slide two, which we show here, provides a summary of my comments on behalf of Abbott. First, we very much appreciate the evaluation by the DME MAC Medical Directors and the medical policy staff in response to Abbott's LCD reconsideration request.

We fully support the proposal to modify the CGM coverage criteria to cover use of CGM systems by beneficiaries with diabetes who are treated with at least one daily administration of insulin or who have a history of problematic hypoglycemia.

We're encouraged that the proposed criteria will help further improve diabetes management consistent with published evidence and accepted standards of care.

Second, we wish to comment on the requirement that patients engage in ongoing six-month visits with their treating practitioner.

We appreciate the clarification that a telehealth visit may serve in place of an in-person visit to meet this requirement.

As I'll discuss, however, we're requesting that the contractors allow additional methods for a practitioner to verify the patient's continued adherence to CGM use, such as remote analysis of the patient's CGM device data.

This change would align this requirement for CGM with the six-month requirement for blood glucose monitoring, which we believe can help reduce confusion and better align these benefits with the clinical evidence discussed in the proposed LCD.

Next slide, please. Thank you.

Slide three addresses the proposal to allow coverage for once daily insulin users or individuals with a history of problematic hypoglycemia.

We support these proposed coverage criteria. In particular, we agree that these proposals align with clinical evidence and professional guidelines as referenced and discussed in the proposed LCD. Accordingly, Abbott agrees and supports the extension of Medicare coverage for CGM systems to these categories of patients beyond intensive insulin users. We request that these criteria be finalized as proposed.

We can move on to the next slide, please. Thank you.

Slide four summarizes the second topic we wish to address related to the ongoing six-month visit requirement. The proposed LCD outlines the importance of regular practitioner visits for improving health outcomes among diabetic patients.

We agree that there are benefits to regular visits between people with diabetes and their treating practitioners and that such visits should be encouraged, but we believe there's an important difference between encouraging regular visits and conditioning CGM access on this visits. For this reason, Abbott remains concerned that the visit requirement for ongoing CGM coverage could still lead to unnecessary disruptions in access to CGM supplies.

This is a particular challenge to meet for populations who have historically faced barriers to accessing primary or specialty care, whether in person or by telehealth.

We believe expiration of the PHE and related telehealth flexibilities will worsen these potential access issues.

Next slide please. Thank you.

And on this slide, we present an alternative standard that we believe would align with current requirements in the LCD that apply to certain BGM users.

We recognize the studies discussed in the proposed LCD demonstrate that regular practitioner visits can help improve diabetes outcomes, but these studies are not specific to CGM patients, nor do they show that the benefits of CGM use can only be achieved with regular six-month visits. For this reason, Abbott does not believe that CGM coverage should be conditioned on regular in person or telehealth visits.

Instead, for example, BGM coverage criteria allow patients using a high volume of testing supplies to continue coverage so long as the treating practitioner verifies adherence to the high utilization testing regimen every six months.

This verification can be documented with a narrative statement regarding the frequency of testing or by including a copy of the beneficiaries testing log in the patient's record.

We request that a similar verification standard be adopted for CGM users through the practitioners' review and analysis of CGM device data.

As I'll describe on the next slide, CGM devices can automatically create a patient log of testing and diabetes management information which can serve the same purpose of verifying adherence. Next slide, please.

Perfect, thank you. On slide six, we provide an example of the type of CGM data that's available to treating practitioners.

The image on the left shows some of the information available through the freestyle LibreView portal.

Practitioner is able to monitor the daily use of the CGM device, as well as verify the patient's time in range, average glucose levels, and variability in glucose levels throughout each day.

We believe that the Glucose Monitors LCD should recognize use of this objective CGM device data and clinical information to document the patient's CGM adherence every six months.

The practitioner can document this adherence without the added expense and barriers to access that may occur with the required in-person or telehealth visit.

We believe this modification would create consistency with documentation requirements for high volume BGM testing, while also aligning with the clinical evidence and recommended standards of care.

Thank you for your time today. I'm happy to address any questions.

Tim Trysla (22:53): Thank you.

Thank you, Doctor Hoover and the DME MAC Medical Directors. My name is Tim Trysla. I am the Executive Director of the Diabetes Technology Access Coalition, or DTAC.

Our coalition represents those who manufacture, develop– and develop diabetes technology, including continuous glucose monitors, the healthcare professionals who prescribe this technology, the patients who benefit from these technologies, and the suppliers who ensure beneficiaries timely– timely receive medical necessary equipment and supplies.

On behalf of DTAC, including our clinician partners, we thank you for this proposed LCD.

We especially appreciate your thoughtful consideration close– and close-review of our reconsideration request, as well as your close attention to the references and studies and additional research you conducted in developing and releasing the proposed LCD. As you will hear from other stakeholders today, this proposed LCD will have result in a significant improvement of Medicare beneficiaries with diabetes. As we will include in our written comments, we wanted to highlight three important items to ensure care continuity to– and to ensure clinically supported access to CGMs.

First, we urge– we urge that you swiftly finalize the proposed CGM LCD. Moving quickly will ensure that beneficiaries who obtain CGMs pursuant to flexibilities during the COVID 19 public health emergency will not face a disruption or gap in care when the PHE ends.

Second, we believe that there are two important elements of the proposed coverage criteria that should be revised to provide greater certainty and stability for beneficiaries with diabetes.

In particular, the language in criterion 4A references a daily administration of insulin; however, we recommend that this be revised to a encompass beneficiaries being treated with any insulin, not only daily administrations.

Further, we ask that you clarify criterion 3 regarding the FDA indications, will not impact beneficiaries who are already prescribed CGMs for medically appropriate purposes under this LCD. Our concern is that the language may be interpreted to mean the beneficiaries will lose access to CGMs if they later develop a condition for which a CGM is not intended.

Finally, we ask that you provide additional detail on the 30-day billing requirements for CGMs. It is unclear to us where this requirement is coming from.

The misalignment between CGM and insulin pump billing cycles creates an unnecessary confusion and disrupts care continuity.

As beneficiaries increasingly use both CGMs and insulin pumps, we believe– we believe the two products should have aligned– should have aligned 90-day billing cycles.

Thank you again for all your hard work in developing this proposed LCD.

DTAC strongly supports the direction and proposed coverage criteria.

We hope that you will incorporate our additional recommendations, which we believe will improve the final LCD, so, that it– it most accurately reflects the clinical evidence available and best supports the beneficiary access to medical necessary– medically necessary diabetes technology.

Thank you again for this opportunity.

Belinda Yandell (26.16): Thank you very much, sir, I'm going to put you back on mute, as we move to our next speaker. That is Linda Langiotti, and I have unmuted your line. Are you available?

Linda Langiotti (26.37): Yes, I'm here.

Belinda Yandell (26.38): Excellent, go ahead.

Linda Langiotti (26.40): Thank you. Hi, this is Linda Langiotti. I'm the Senior Vice President of Strategic Channel with CCS Medical. CCS Medical is a supplier that serves over 100,000 Medicare beneficiaries living with diabetes. Our experienced and size, makes us well versed in the needs of the market. I think you will find that we are a passionate advocate for beneficiaries we serve, and our comments today reflect decades of experience servicing Medicaid beneficiaries who live with diabetes.

First, we would like to thank the DME MACs efforts to ensure Medicare beneficiaries have access to innovative diabetes technologies, and support most of the proposed changes in today's CGM proposed document. We appreciate your continue support to reduce the administrative burden for providers, beneficiaries, and suppliers alike, to ensure that Medicare beneficiaries have timely access to the right technologies to help manage their diabetes.

Like many others before me on this call, we would like to take the opportunity to provide feedback on the proposed changes to the LCD regarding the new criterion three that the CGM must be prescribed to FDA indica… indicated use.

We believe that this criteria would be an unprecedented move that we have not seen before in local coverage determinations, and we're also concerned that this addition of criteria will have negative, unintended consequences for some Medicare beneficiaries. For example, the beneficiary currently qualifies for CGM under the coverage criteria, but later develops a condition for which CGM does not have an FDA indication, then beneficiary could lose access to the CGM. It should not be up to us as suppliers to interpretate, interpret criterion of the FDA

indications but, rather up to the prescribing provider and the beneficiary to determine when it is appropriate for a beneficiary to be on CGM therapy.

The DME MACs should trust the providing, the providers to prescribe CGM therapy appropriately.

Also, a beneficiary who otherwise meets the coverage criteria should be able to get CGM. We do not see that the addition of criterion three as a prevention tool for those who do not need to be on CGM therapy, but rather a limitation to access for those who are currently benefits, benefit, benefiting from CGM therapy.

Like others before me our second comment is regarding the 30 day billing cycle for CGM supplies. The DME MACs stated in the proposed rule that the request to align the 30 day billing cycle for CGM supplies with 90 days billing cycle, 90 days still applies for billing supplies was not under their purview.

We understand that that this may not be something that you can immediately fix, but we do request that you support those of us who are looking to fix this requirement.

The 30 day billing restriction was implemented for CGM Supplies because CGM was an emerging technology at the time it was first covered, that's what we believe; however, as the proposed LCD confirms CGM is no longer a new technology and, and a standard, is now a standard of care for all of those living with diabetes.

We believe the purpose of the billing restriction for CGM supplies comes from ensuring that beneficiaries are continuing to use their CGM and using their CGM supplies appropriately. The reality of our last five years as a supplier servicing Medicare beneficiaries on CGM therapy, is we see the beneficiaries are compliant with the therapy the majority of the time.

The removal of the 30 day billing restriction will better align the beneficiary that there are other diabetes supplies, as previously mentioned, especially with insulin pumps. Most of the beneficiaries are using closed loop systems so, this would be, make life a lot easier for the beneficiary as well.

I think the biggest thing for us as a supplier is trying to explain to the beneficiary why they can't get all their supplies aligned.

So, for some beneficiaries, they can be on an insulin pump with a 90 day shipment and billing cycle.

They can be on diabetes testing supplies for calibration on a 90 day shipment and billing cycle, and then their CGM supplies can be a 90 day shipment, but a 30 day billing cycle, and it's very confusing for the beneficiaries, and they have expressed a great deal of frustration to us as suppliers.

So, we believe that DME MACs are uniquely positioned to help educate CMS on why making the change to this potential billing cycle would be an improvement for beneficiary access and reduce the unnecessary paperwork burden for both suppliers and the DME MACs.

Lastly, we urge you to finalize the proposed LCD in alignment to the exit of the public health emergency as others have previously stated. Medicare beneficiaries who did not qualify for CGM under the current LCD criteria may have been using a therapy during the PHE. For CCS Medical, these beneficiaries have medical necessity reasons for being on CGM therapy, and many would qualify for CGMs under the proposed LCD, and we do not want to see a gap in access for beneficiaries. We thank you for the opportunity to comment, and we will be submitting our written comments as well.

Belinda Yandell (32:10): Thank you, Linda Langiotti. I'm re-muting your line.

We appreciate your comments, as we move forward to Doctor Egils Bogdanovics.

Let me find you here on our list.

There we go. I've unmuted you.

Doctor, Doctor Bogdanovics I'm showing that you are self-muted.

If you could unmute your line, please.

I believe you've got access now. (Inaudible)

Egils Bogdanovics (33:00): All right, great. Thank you, thank you, good morning. (Inaudible) My name is Egils Bogdanovics, I'm a practicing endocrinologist, the director of a Diabetes center in Connecticut, Assistant Clinical Professor at University of Connecticut School of Medicine, but most importantly, a person with type 1 diabetes for the last 40 plus years, thus intimately familiar with the nearly miraculous benefit of continuous glucose monitoring.

I have not been solicited to comment by any of the manufacturers, in fact, I've personally and professionally used most all commercially available CGM devices.

CGM is now standard of care for patients with diabetes on both multiple daily insulin injection therapy or continuous subcutaneous insulin infusion, and it's been endorsed by the American Diabetes Association and the American Association of Clinical Endocrinologists. Both professional societies also recommend CGM for adults with diabetes, unless intensive insulin therapy, such as basal insulin.

It is very satisfying to see that CMS is considering broadening the coverage for CGM based on these guidelines.

During the COVID Public Health Emergency, I used CGM in multiple people with diabetes that did not otherwise qualify.

These included patients on daily basal insulin, patients on oral agents, and pregnant patients.

For the newly diagnosed patients on oral agents, it gave them nearly immediate feedback as to the effect of the lifestyle modifications that were prescribed by my diabetes team.

One saw a trend arrows going straight up after a bagel, with trend arrow's flat after a couple of fried eggs.

Another one saw the effect of biking for 30 minutes on flattening glucose rise.

For those patients later in their diabetes journey, CGM shows what is happening between meals.

The rise and fall we've been missing for years, using just finger stick blood glucose monitoring. The untapped potential of CGM in improving the quality of life, as well as the A1C of our patients is enormous.

Although the, uh, plural of these anecdotes is certainly not data The proposed LCD summary of evidence and literature analysis that you put together provide a robust review of current evidence

for the use of CGM in patients treated with basal insulin. I'd like to highlight just one, the trial by Martens et al. showing that patients on basal insulin, using CGM, had 3.5 more hours in target range than those patients using conventional glucose monitoring. But it's important to note that these were typical patients, including half from ethnic and racial minority groups, and they were followed by primary care providers, not diabetes specialists, and they did not receive any specific instructions or significant increase in their medications.

By simply wearing a continuous monitor, one is enabled to visualize the effect of lifestyle on glucose control in real time and improve control, potentially, as much as the addition of another diabetes medication.

Furthermore, actually decreasing the risk of hypoglycemia rather than increasing medication associated iatrogenic hypoglycemia.

It is important that all of our primary care providers be enabled to use this tool early in the course of diabetes. Particularly in the setting of the shortage of endocrinologists, and the need to alleviate health disparities.

The cost of supplies is significant, but the cost of poorly treated diabetes is staggering.

As I mentioned earlier, I'm an endocrinologist but, I also have been managing my own diabetes for 40 years.

When I was diagnosed, fingerstick monitoring was brand new, and I checked urine, as well as using this new technology called FMBG.

I've got a history of life-threatening, severe hypoglycemia prior to CGM use. I've had no significant hypoglycemia bouts in the last fifteen years while using CGM.

Fortunately, my insurer has covered the supplies.

I cannot overemphasize how it has changed my life and improve the lives of all of my loved ones.

But it's not just for avoiding hypoglycemia.

My glucose control and the control of my patients has markedly improved with the use of CGM and the immediate feedback on the effective food, medications, and exercise on blood glucose.

Recently, some CGM manufacturers have lost sent, have launched sample programs for short patient trials.

Even my most reluctant device agnostic patients have taken part in these trials, and the response is always the same, "How fast can I get my own?"

The time has come that every person with diabetes be given the option of using a continuous glucose monitor.

CMS has to be commended for leading the way in removing barriers to their access with this proactive coverage determination.

This is the most important tool we have to improve diabetes control, as well as the quality of life for our patients with diabetes.

Thank you for the opportunity to comment, and for your attention.

Belinda Yandell (38:50): Thank you, sir. I'm going to put you back on mute now, as we move forward to our next speaker, and that is George Colony, and let me get your line open.

George Colony (39:09): (Inaudible) Can you hear me?

Belinda Yandell (39:12): Yes, there you are. Go right ahead, sir.

George Colony (39:15): Hello, everyone. My name is George Colony, and I'm the founder of Med Supply US. We are a DME supplier who focuses on providing, providing care for diabetic patients. I wanted to say thank you for the opportunity to speak, and amazing job with the proposed LCD. Everyone has done a very thorough review of the evidence, and this is a very positive step forward.

I agree with all of the comments that everyone has mentioned, and we're really grateful that you're expanding the coverage because we hear from people daily, and this expansion will really help people live more peaceful, better lives.

One thing I just want to touch on is, we do have a lot of patients who have been able to get a CGM during the public health emergency, so I would encourage you to push this forward, before the PHE ends.

That way there's no gap in coverage, and we also agree with Mahmood from Abbott about the documentation in the chart notes that he mentioned.

I agree with the telehealth visit but, also, if, if we could use the data from the CGM to, to show that the patient is using the device, and it's, and it's helpful, because there's a lot of providers that don't necessarily always put the same information. So, if we could use the data from the CGM to show it, that would really help patients, doctors, and suppliers.

We also agree with the comment about being able to bill for 90 days' worth of supplies because there's a lot of stuff that, that can happen if we're sending a three month supply, a 3 month supply to a patient, billing every 30 days, and sometimes it gets stressful for the patients, like some others mentioned.

So, yes, I just had some brief comments; wanted to give you a perspective from someone who's speaking to patients every single day from the supplier's end.

I think this is a great step forward, and thank you guys very much.

Belinda Yandell (41:29): Thank you, Mister Colony. I am going to put you back on mute, as we move forward to our next speaker that Janet McGill, and Janet, I am unmuting you. Go right ahead.

Janet McGill (41:48): Ok. So, thank you very much, very much thanks to the LCD committee, to CMS for moving these recommendations into what we consider real life practice in diabetes. I'm a Professor of Medicine at Washington University. I'm an endocrinologist. I have treated patients with type 1, type 2, monogenic, steroid induced, other kinds of diabetes, for 35 years. I worked with the Diabetes Technology Access Coalition. My conflicts of interest are that we finished a Medtronic Pump Study a couple of years ago, finished a Bionic Pancreas Study last year But, I have no other conflicts of interests with the CGM providers. So, a couple of things, one is we absolutely applaud this current recommendation, and we would like just some very minor adjustments.

First of all, administration of insulin once per day seems like a very reasonable approach and is supported by the mobile study by Martens.

We note that once per week insulin is on the horizon and for that reason, plus patients who may be on and off insulin, and I'm thinking our chemotherapy patients who require high dose steroids then they're off for a period of time then the required again. We are currently putting as many of these patients on CGM as we can because it is so confusing for them how to manage their insulin requirements in this very difficult time.

So, any insulin administration would help us tremendously. Regarding the limitation that a CGM must be administered as it is FDA approved, I would remind the committee that insulin is not FDA approved for patients with end stage kidney disease.

Only recently, has FDA required study of medications in patients with advanced kidney disease. So, the majority of our medications do not have FDA approval for these patients, and they don't have FDA approval for use in pregnancy.

So as clinicians, we must treat these very high risk patients. We know how to treat them. We know what their limitations are, and we use CGM.

It is particularly helpful to use automated insulin delivery in patients who are either pregnant or at very high risk of hypoglycemia.

So, we would ask, LCD to limit their recommendations, not, to not limit recommendations rather, and for now, use of any insulin would be appropriate.

We also encourage finalizing these recommendations prior to the end of the public health emergency, and we really just want to thank you for listening to us, and for providing this opportunity to add both verbal and written comments, because as Doctor Bogdanovics said, "CGM is as valuable as another medication." The difference is that it's safer than another medication. We use CGM to both bring patients glucoses in range, and to prevent life threatening hypoglycemia, and with that, I'll stop. Thank you, very much.

Belinda Yandell (46:09): Thank you, Janet.

I put you back on mute, and we proceed now to Donald Jani.

I believe I'm showing you as self-muted.

Donald Jani (46:28): Oh, hi. Uh, sorry about that. So, my name is Don(inaudible), and I am the owner of CSS Pain Relief. We do provide medical supplies basically, to Um, glucose or, you

know, insulin dependent patients. We've been working, or we've been working, since about the last two years.

The most common issues that we've come across is almost is being, you know, unanimously covered by everyone, that some patients they don't take enough insulin today to qualify for, um, coverage through Medicare, but because of public health emergency, there was some room that was made, uh, otherwise the 30 day limitations for billing and shipping as well. Where, for example just in the recent time, when we had a Hurricane Ian, we could not supply a lot of patients with their supplies on time.

Because of that, some of them got really upset, and they, they, they say that they would (inaudible) get their supply sooner than later, but logistical issues, we really couldn't do much.

But other than that, I guess most of the other intellects over here on this panel have already spoken a lot, and they know of things better than anything else.

So, I, I'd rather put that to rest right now. But all the, all the recommendations are all valid. I don't see any problem with them.

One time insulin a week as well, is something that we get a lot, you know, patients, they want to be in control of their glucose levels, even though it's just one time, one time a week. So, I'd rather, that's all I had to contribute. Thank you.

Belinda Yandell (48:35): Thank you, sir. I've put you back on mute, as we move ahead to our next speaker, and, let me find you here, and that would be Robert Gabbay.

Robert Gabbay (48:56): Yes, thank you so much.

Good morning, Doctors Ballyamanda, Brennan, Hoover, Jenny, and Lalla, and thank you so much for the opportunity to provide comments. My name is Doctor Robert Gabbay. I'm the Chief Scientific and Medical Officer here at the American Diabetes Association. I'm an endocrinologist by training, and I continued to see patients at the Joslin Diabetes Center, where I used to be the Chief Medical Officer. Next slide, please.

Uh, as a reminder, the American Diabetes Association is a (inaudible)nationwide, non-profit, voluntarily health organization, founded in 1940, that represents persons with diabetes, the health care professionals, that care for them, research scientists and other concerned individuals, and our mission is to prevent and cure diabetes and improve the lives of all of those people affected by diabetes.

We're the largest non-governmental organization that deals with the treatment and impact of diabetes and represent the 133 million people living with diabetes and pre-diabetes, and have more than 500,000 general members, 15,000 health professionals, and one million volunteers.

The day after World Diabetes Day, we're reminded of the important vision of a life free of diabetes at all its burdens.

We very much appreciate CMS, DME MACs, leadership, and continued focus on ensuring CGM products are as accessible as possible to Medicare beneficiaries, both during the public health emergency and permanently, and really acknowledge appreciation for a number of recent decisions.

Including the removal of four times a day, testing, the change from injection to administration of insulin as part of the requirements, the reimbursement for adjunctive CGMs as a Part B benefit, which was included in the December 2021 rulings.

Each of these has really lead to broader access. The next slide, I want to just frame our discussion today a bit more broadly and, you know, what are the things that the COVID Pandemic has really highlighted was the disproportional toll it had, not only on people with diabetes, but on minority and low income, and historically underserved Americans. It's really shed a trouble, a light on this systemic inequities that exist in health care.

That is why the ADA's Health Equity Bill of Rights has envisioned a future without these unjust health disparities, so that no matter what an individual's race, income, zip code, age, education, or gender, that they get equal access to the most basic of human rights, their health, Next slide.

So, technologies like CGM have literally transformed diabetes management, and you've heard some examples of that, and I certainly can echo those with my patients. Literally, they speak of this as a game changer in their lives and could never imagine not having access to CGM.

It's also been demonstrated in studies to improve outcomes, and make it easier to live with diabetes but, for many, access remains financially out of reach and, like other diabetes technologies, availability is often determined by, you know, what one's zip code is, and large

numbers of minorities live in less affluent zip codes, and this really impairs their ability to have access, and this is not only for people with type 2 diabetes but, we know that for individuals with type 1 diabetes, Black, Black, and Latin (inaudible) adults, also are less likely to have access.

Uh, so, as you're aware, the ADA Standards of Care that have been cited a number of times here this morning, is published annually. It is recognized as the gold standard for professionals in the medical field, in terms of how to manage best care for people with diabetes. It is developed by a group of experts, after exhaustive review of the literature, and it is highly evidence based, and it, states very clearly that any person taking insulin should have continued access across third party payers, and that the type and selection of CGM device should be individualized, based on the person's specific needs, desires, their skill level, and the availability of the devices.

We really want to applaud the DME MAC medical directors for expanding access to Medicare beneficiaries, and our sincere hope is that Medicaid program and commercial payers will follow suit.

Next slide.

So, like the other speakers, the ADA, wholeheartedly supports the provisions that have been proposed, and really applaud the removal of several of the unnecessary barriers and criteria's as well as the addition of new items, and then had a couple of suggestions to further improve this. The, the first that we think, is really a wonderful addition and aligns with the Standards of Care that we're just published this year, is that beneficiaries treated with insulin at least once daily should be eligible and moving away from the multi-dose, and as, as you all acknowledge, it's really based on randomized controlled trial evidence to show benefit, the one adjustment would be one that has been mentioned previously, that as, as, for example, the FDA will soon be reviewing once weekly insulin, that the language should recommend, should be written as the beneficiary is treated with insulin, and not be more specific than that.

Belinda Yandell (56:38): Doctor Gabbay, let me interrupt you. We've reached your time limit if you'd like to wrap this up.

Robert Gabbay (56:45): Oh, yes, I'm sorry, ok. So, appreciate the important work that the group is doing. The frequent adjustment of insulin is, is important, and the hypoglycemia issue is also important, and we, we appreciate that definition. I will finally say that allowing the beneficiaries access that had access during public health emergency, I think, is particularly important to let them have continued to access. These include individuals that their clinicians felt would be beneficial, some of them are on sulfonylureas, and we ask that, that be ...

Belinda Yandell (57:33): Doctor Gabbay, I've had to cut you off, as we have to move forward. I'm so sorry about that.

It is time for our closing remarks.

So, I'll turn this back over to Doctor Robert Hoover.

Robert Hoover (57:47): Thank you, Belinda, and again, we'd like to thank all members of the public and stakeholders for your thoughtful comments today.

Please remember to send your comments in writing, and that if you have any full text, peer reviewed articles to help support your comments, that are not included in our bibliography, please send those along as well.

As I noted earlier, the comment period will end this Saturday, November 19th.

Once we have collated and considered all the comments received during the open comment period, we'll make any changes necessary as a result of the comments received and then, post the final LCD along with a response to those comments in a document form.

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.

I want to thank Belinda for moderating our call today, and everyone who participated in today's call. We look forward to your written comments.

We'll adjourn the meeting at this time. Thank you for participating.

Belinda Yandell (58:53): Thank you all. This is your moderator; I am about to end the meeting. Thank you very much.