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Micheal K. Smith, *Secretary*
[phone] 802-241-0440
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Date: October 15, 2021

Re: Response to Public Comments for Global Commitment Resister (GCR) Policy 21-041, Continuous Glucose Monitors Available Through Pharmacy Benefit

The Department of Vermont Health Access (DVHA) response to public comments on this policy change is below. The comments received, which raised concerns about prior authorizations, coverage criteria, and the impact on patients who may no longer qualify for coverage, are enclosed in the pages following the response.

Response: Thank you for your interest and public comments on GCR policy 21-041, Continuous Glucose Monitors Available Through Pharmacy Benefit. Please find the information below in response to your comments.

DVHA modified its prior authorization criteria effective October 1, 2021. Specifically, the department removed the requirement for *"at least three injections per day"*. The department also removed the requirement for *"frequent adjustments to treatment regimen are necessary based on blood glucose testing results"* and removed all the following requirements:

At least one of the following are documented: Hypoglycemic unawareness; recurrent episodes of severe hypoglycemia (<55 mg/dL) or hyperglycemia (>300 mg/dL) persisting despite adjustments to therapy based on previous short-term CGM or self-monitoring; nocturnal hypoglycemia; patient cannot achieve glycemic control (defined as HbA1c ≤ 7%) despite good compliance and understanding of current treatment plan; Note: pharmacy claims will be reviewed for the past 6 months to assess compliance; and recurring diabetic ketoacidosis.

The criteria now requires that someone have *"multiple daily injections with a rapid or short acting insulin, or is on an insulin pump"* to qualify. The current criteria allow access for either Type I or Type II diabetics. This is less restrictive than Medicare guidelines which require three (3) daily injections. It is also aligned with 2021 American Diabetes Association standards of care where the strongest level of evidence supports recommended use of continuous glucose monitors in conjunction with multiple daily injections and continuous subcutaneous insulin infusions (American Diabetes Association, Diabetes Care 2021 Jan; 44(Supplement 1): S85-S99 https://doi.org/10.2337/dc21-S007).

DVHA's criteria was reviewed and approved by the Drug Utilization Review Board in July 2021 and appears below.

In addition to the changes to criteria, as a result of public comments received, Medicaid members currently on a continuous glucose monitor will be allowed to continue to have coverage of their

devices, even if they do not qualify for continued use under the current prior authorization criteria.

Preferred Drug List coverage criteria for continuous glucose monitors:

CONTINUOUS GLUCOSE MONITORS		
Initial approval will be granted for 6 months; renewals up to 1 year thereafter		
Preferred After Clinical Criteria Are Met DEXCOM G6 **Initial prescription:** 1 receiver, 1 wireless transmitter, and 1 3-pack of sensors	Medtronic Guardian™ Connect **Initial Prescription**: 1 transmitter, 5 sensors **Refill Quantity Limits:** 1 transmitter every year, 1	Patient has a diagnosis of Diabetes Mellitus AND • 2 years of age or older for Dexcom G6, ≥ 14 years for Medtronic Guardian, or ≥ 4 years for Freestyle Libre 2, or ≥ 18 for Freestyle Libre AND

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PREFERRED AGENTS (No PA required unless otherwise noted)	NON-PREFERRED AGENTS (PA required)	PA CRITERIA
Refill Quantity Limits: 1 transmitter every 3 months, 1 sensor every 10 days (maximum of 9 sensors every 90 days) FREESTYLE LIBRE PRO (10-DAY SENSORS) **Initial Prescription:** 1 reader, 3 sensors **Refill Quantity Limits:** 1 sensor every 10 days (maximum of 9 sensors every 90 days) FREESTYLE LIBRE 14 DAY (14-DAY SENSORS) **Initial Prescription:** 1 reader, 2 sensors **Refill Quantity Limits:** 1 sensor every 14 days (maximum of 6 sensors every 84 days) FREESTYLE LIBRE 2 (14-DAY SENSORS) **Initial Prescription:** 1 reader, 2 sensors **Refill Quantity Limits:** 1 sensor every 14 days (maximum of 6 sensors every 84 days)	sensor every 7 days (maximum of 5 sensors every 35 days) Medtronic 670G Guardian Link 3 **Initial Prescription:** 1 transmitter, 5 sensors **Refill Quantity Limits:** 1 transmitter every year, 1 sensor every 7 days (maximum of 5 sensors every 35 days) Medtronic 770G Guardian Link 3 **Initial Prescription:** 1 transmitter, 5 sensors **Refill Quantity Limits:** 1 transmitter every year 1 sensor every 7 days (maximum of 5 sensors every 35 days) Medtronic MiniLink (includes Enlite Serter) **Initial Prescription:** 1 transmitter, 5 sensors **Refill Quantity Limits:** 1 transmitter every year, 1 sensor every 7 days (maximum of 5 sensors every 35 days)	• Patient requires multiple daily injections of a rapid/short acting insulin or is on an insulin pump. • Approval of non-preferred products will be limited to cases where the CGM is directly integrated with the patient's insulin pump. The make and model of pump must be documented on the prior authorization. **Re-authorization:** • There is documented evidence of compliance to CGM (log data and/or office visit notes required). • Replacement will be considered when medically necessary and not for recent technology upgrades (device must be malfunctioning and out of warranty).

Testimony- Public Comment for Reinstatement of CGM Criteria for Vermont Medicaid

The FreeStyle Libre 2 system is the latest version of the FreeStyle Libre Portfolio. It is the most widely used Continuous Glucose Monitor (CGM) worldwide.[*] [1] The adult percentage of diabetes is ~7.6% in the State of Vermont, with type 2 diabetes being most prevalent. Both the intensified insulin users and basal insulin using type 2 population has been benefiting from the utilization of CGM during the Covid 19 pandemic. We respectfully request that the three multiple daily injections or insulin pump requirement be removed to allow the type 2 diabetes basal using population to continue to benefit from CGM technology.

It is the only 14-day integrated CGM (iCGM) with real-time alarms[†]. A quick scan of the sensor allows the user to see current glucose, 8 hours of glucose history, and glucose trend arrows. The water-resistant sensor[‡] is the thickness of 2 stacked quarters.[2]

Other features include:

- Indicated for management of diabetes in persons age 4 and older.
- Unsurpassed 14-day accuracy[3] with an overall MARD of 9.2% for adults (ages 18+) and 9.7% for pediatrics (ages 6-17); [3] glucose data can be used to make insulin dosing decisions without fingersticks.[§]
- Real-time alarms[†] for hypoglycemia, hyperglycemia, and signal loss, which automatically notifies the user when glucose levels go beyond the target range[||] set by the patient, or when the signal is lost, without the need for scanning.
- Glucose readings every minute[4] – 5 times more readings than other iCGM systems.[5] This allows notifications[†] the minute glucose goes out of range. [4,5,||]
- Built-in transmitter - This reduces the risk of patients not being able to use the system due to lost transmitter and then incur an additional cost associated with transmitter replacement.
- FreeStyle Libre 2 iOS app allows users to check their glucose with a compatible iPhone[¶] every minute with real-time glucose alarms[#]. The FreeStyle Libre 2 app enables kids (ages 4 and older) and adults to easily[2] share their glucose data with parents and other caregivers via the LibreLinkUp [Δ,**, ††] app.

The FreeStyle Libre Portfolio has been associated with reductions in hypoglycemia, A1C, and resource utilization:

- Two separate, prospective randomized controlled trials demonstrated ~40% reduction in duration of hypoglycemia compared with blood glucose monitoring for adults with type 1 diabetes (T1D) and type 2 diabetes (T2D) on multiple daily injections (MDI) insulin therapy.[6,7, ‡‡]
- In a meta-analysis, the FreeStyle Libre Portfolio was associated with an average A1C reduction of 0.55%. Results were similar for adults and pediatrics, and T1D and T2D. This reduction was observed within the first 2 months and sustained over 12 months.[8, ‡‡]
- Retrospective, observational analysis using data from the US IBM Explorys revealed that FreeStyle Libre Portfolio prescription was associated with a reduction in A1C for T2D patients on basal insulin or non-insulin therapy.[10, ‡‡] The magnitude of reduction was 1.1% and 1.6% in the basal insulin (N=306) and non-insulin regimens (N=728) respectively.[9, ‡‡]
- Retrospective, observational analysis using data from the US-based IBM MarketScan database of T2D patients on MDI (N=2,463) revealed that FreeStyle Libre Portfolio acquisition was associated with a 60% reduction in acute diabetes events rates, and 33% reduction in all-cause hospitalizations over 6 months.[10, ‡‡]
- Previous research has indicated that costs associated with hospitalizations for acute diabetes events are significant.[11,12] It is estimated that hospitalizations for severe hypoglycemic episodes range anywhere between $9,670 - $11,989 per event.[11] Additionally, hospitalizations for diabetic ketoacidosis costs around $26,566 per event.[12]

Disclaimers, References, and Important Safety Information on Pages 3 and 4

In addition to the reduction in health resource utilization, there are cost reductions from better A1C control.

- Analysis published by ADA estimates that cost of diagnosed diabetes in US is about $327 billion.[13]
- A study using US IBM MarketScan database revealed that for people with T2D (N=77,622) a 1% reduction in A1C was associated with a 2% reduction in all-cause total health care costs and a 13% reduction in diabetes-related costs, that translates to an annual savings of $429 and $736 per patient.[14]
- Large repository of US health plan administrative data identified 3,197 patients with A1C >9%. Researchers observed that those who experienced a reduction in A1C had a 24% reduction in healthcare costs in the first year, and 17% reduction in second year compared to those who did not experience an A1C reduction. This translates to a savings of $2,503 and $1,690 per patient per year.[15]

Recently, the American Diabetes Association's 81st Scientific sessions highlight a growing body of clinical evidence around the benefits of FreeStyle Libre Portfolio systems:

- In comparative real-world analysis for US-only matched patient groups, the FreeStyle Libre Portfolio systems was shown to achieve similar reductions in A1C compared to other CGM systems.[16, ‡‡] Additionally, similar rates of acute diabetes events and hospitalizations were observed patients following acquisition of FreeStyle Libre Portfolio systems and other CGM systems.[17, ‡‡]
- FreeStyle Libre Portfolio systems reached a much wider, more diverse population than other CGM systems.[16,17, ‡‡]
- Increased use of FreeStyle Libre Portfolio systems is cost-neutral for Medicaid plans as a result of reduced health resource utilization from better glycemic control. [‡‡,18] In a budget-impact analysis (Medicaid perspective), researchers found that increasing adoption of FreeStyle Libre Portfolio systems by 10% among T1D and T2D multiple-daily injection users was associated with a $0.31 per-member-per-year (PMPY) annual budget reduction after accounting for acquisition costs, costs offsets from A1C reductions, and costs of diabetic ketoacidosis and severe hypoglycemic events.[18, ‡‡]
- A multi-center, retrospective chart review (N=100) analysis across 8 centers in US revealed that FreeStyle Libre Portfolio system acquisition was associated with a 1.4% reduction in A1C over 3-6 months in patients with poorly controlled T2D (A1c $\geq$ 8%) on basal insulin therapy.[19, ‡‡] These findings were validated in a meta-analysis (N=191) of retrospective chart reviews across multiple sites in US and Canada with A1C reduction of 1.1% among patients with poorly controlled T2D on basal insulin therapy. [20, ‡‡]

FreeStyle Libre 2 system is easy to use[‡‡,6,7] and more affordable[§§].

*Data based on the number of users worldwide for FreeStyle Libre family of personal CGMs compared to the number of users for other leading personal CGM brands and based on CGM sales dollars compared to other leading personal CGM brands.

†Notifications will only be received when alarms are turned on and the sensor is within 20 feet of the reading device. You must have Critical Alerts enabled to receive alarms and alerts on your smartphone.

‡Sensor is water-resistant in up to 1 meter (3 feet) of water. Do not immerse longer than 30 minutes.

§Fingersticks are required if your glucose alarms and readings do not match symptoms or when you see Check Blood Glucose symbol during the first 12 hours

||Default range is 70-180 mg/dL. Consult with a healthcare professional on individual target glucose range.

¶The FreeStyle Libre 2 app is only compatible with certain mobile devices and operating systems. Please check our website for more information about device compatibility before using the app. Use of the FreeStyle Libre 2 app requires registration with LibreView.

#The High Glucose alarm level can be set between 120-400 mg/dL and the Low Glucose alarm level can be set between 60 – 100 mg/dL Notifications will only be received when alarms are turned on and the sensor is within 20 feet of the reading device. Critical Alerts must be enabled to receive alarms and alerts on the smartphone.

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Δ The LibreLinkUp app is only compatible with certain mobile devices and operating systems. Please check www.librelinkup.com for more information about device compatibility before using the app. Use of the LibreLinkUp app requires registration with LibreView. Dosing decisions should not be made based on this device. The user should follow instructions on the continuous glucose monitoring system. This device is not intended to replace self-monitoring practices as advised by a physician.

**The user's device must have internet connectivity for glucose data to automatically upload to LibreView and to transfer to connected LibreLinkUp app users.

††Glucose alarms will transfer to the LibreLinkUp app users when users are connected and alarms are enabled on the FreeStyle Libre 2 app.

‡‡Data from this study were collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 2 has the same features as FreeStyle Libre 14 day system with optional real-time glucose alarms. Therefore the study data are applicable to both products.

§§Based on a comparison of list prices of the FreeStyle Libre 2 system versus competitors CGM systems, assuming annual use of one receiver (or equivalent hardware) and quantity of transmitters and/or sensors according use life. The actual cost to patients may or may not be lower than other CGM systems, depending on the amount covered by insurance, if any.

References:

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Important Safety Information

FreeStyle Libre 14 day system: Failure to use FreeStyle Libre 14 day system as instructed in labeling may result in missing a severe low or high glucose event and/or making a treatment decision, resulting in injury. If readings do not match symptoms or expectations, use a fingerstick value from a blood

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glucose meter for treatment decisions. Seek medical attention when appropriate or contact Abbott at 855-632-8658 or https://www.FreeStyle.abbott/us-en/safety-information.html for safety info.
FreeStyle Libre 2 system: Failure to use FreeStyle Libre 2 system as instructed in labeling may result in missing a severe low or high glucose event and/or making a treatment decision, resulting in injury. If glucose alarms and readings do not match symptoms or expectations, use a fingerstick value from a blood glucose meter for treatment decisions. Seek medical attention when appropriate or contact Abbott at 855-632-8658 or https://www.FreeStyle.abbott/us-en/safety-information.html for safety info.

Disclaimers, References, and Important Safety Information on Pages 3 and 4

Wednesday 29 September 2021

RE: GCR 21-041

Dear Medicaid / *Change Healthcare* Policy Makers:

I ask that you please do ***not*** limit approval of **continuous glucose monitoring (CGM)** to only people with diabetes (PWD) on multiple daily injections (MDI) of short-acting insulin. The use of CGM is such a useful tool that helps us in the management of PWD who are are not on MDI insulin when self measurement of blood glucose (SMBG) and HbA1c are not adequate to make a good assessment. CGM is useful for measuring **Time in Range** (TIR) for detecting PWD who have wide Glucose Variability (GV) i.e., are on a "roller coaster", that can be easily missed by SMBG and a falsely reassuring HbA1c (which is only a measure of the average). Low TIR with high GV are equally important markers for adverse outcomes as is a high HbA1c, frequently not easy to detect by SMBG.

I recommend that the current proposed Prior Authorization use criteria which state:

Patient has a diagnosis of Diabetes Mellitus AND meets BOTH criteria below:

- ☐ Patient requires use of insulin at least three times per day or is on an insulin pump.
  Make and Model of insulin pump: _____
- ☐ Frequent adjustments to treatment regimen are necessary based on blood glucose testing results

AND At least one of the following are documented for NEW requests (documentation must be submitted):

- ☐ Hypoglycemic unawareness
- ☐ Recurrent episodes of severe hypoglycemia (<55 mg/dL) or hyperglycemia (>300 mg/dL) persisting despite adjustments to therapy based on previous short-term CGM or self-monitoring.
- ☐ Nocturnal hypoglycemia
- ☐ Patient cannot achieve glycemic control (defined as HbA1c ≤ 7%) despite good compliance and understanding of current treatment plan. (Note: pharmacy claims will be reviewed for the past 6 months to assess compliance). HbA1c results:_____Date obtained:_____
- ☐ Recurring diabetic ketoacidosis

Be *amended* as follows:

Patient has a diagnosis of Diabetes Mellitus AND meets ~~BOTH~~ **ONE OR MORE** criteria below:

- ☐ Patient requires use of insulin ~~at least three times per day~~ or is on an insulin pump.
  Make and Model of insulin pump: _____
- ☐ Frequent adjustments to treatment regimen are necessary based on blood glucose testing results

~~**AND** At least one of the following are documented for NEW requests (documentation must be submitted):~~

- ☐ Hypoglycemic unawareness
- ☐ Recurrent episodes of severe hypoglycemia (<55 mg/dL) or hyperglycemia (>300 mg/dL) persisting despite adjustments to therapy based on previous short-term CGM or self-monitoring.
- ☐ Nocturnal hypoglycemia, documented or suspected

☐ Patient cannot achieve glycemic control (defined as HbA1c ≤ 7%,Time in Range ≥ 70% or Glucose Variability < 36%) despite good compliance and understanding of current treatment plan. (Note: pharmacy claims will be reviewed for the past 6 months to assess compliance). HbA1c results:_____Date obtained:_____

☐ Recurring diabetic ketoacidosis

☐ And other conditions as may be clinically appropriate. Please describe:

_____

Any one of these criteria by themselves present as situations that are frequently difficult to manage by SMBG alone, such as asymptomatic nocturnal hypoglycemia which usually leads to rebound fasting hyperglycemia which until the nocturnal hypoglycemia is discovered, leads the clinician to prescribe stronger doses of drugs making the situation worse instead of better and putting the PWD at increased risk of a severe adverse event with hospitalization or even death. This can happen with once daily injections of long-acting insulin (called "over-basalization"), with oral sulfonylureas and even with metformin in a patient whose diabetes is mild and is very sensitive to usual doses of metformin. CGM can be a lifesaver here by unmasking the nocturnal hypoglycemia that would be difficult to detect by using SMBG alone.

CGM has also been useful for my diabetics who for whatever reason cannot do SMBG (e.g., too painful, bleed too much from being anticoagulated, very thick skin, cognitively challenged). For these patients, intermittent short term CGM for 10 to 14 days prior to each diabetes follow up appointment has been instrumental in assessing their control.

There are also some other benefits to CGM, such as greater patient engagement in their own care resulting in improved outcomes. Thus extra money spent upstream on expanded use of CGM to achieve better control will save a lot more money downstream by avoiding complications whose management and treatment is much more expensive.

In summary:

Although SMBG is very suitable and sufficient for many diabetics on oral medications and fewer than 3 daily injections of insulin, it can easily "miss the mark" when there is actual or suspected nocturnal hypoglycemia or hypoglycemic unawareness.

Time in Range is as equally important as HbA1c in assessing overall control, and although this can be estimated using structured SMBG, it can be difficult to measure adequately at times with SMBG, and we need the help of CGM in those situations.

Sincerely yours,

Gregory King, MD
Board Certified Family Physician
Mt. Anthony Primary Care
655 Main St.

From:	Lucy Gordon
To:	AHS - Medicaid Policy
Subject:	from Lucy Gordon RN CDCES
Date:	Tuesday, September 14, 2021 8:43:51 AM
Attachments:	image001.png

Please consider extending benefits for use of glucose monitoring using flash or continuous technology to all people with diabetes.

Within my clinical practice I see how the use of these technologies provides clients with agency and motivation to manage their diabetes in daily practice.

I have seen first-hand how continuous data reveals hypo-hyperglycemia events not otherwise detected with 1-2 capillary readings per day.

The expense of diabetes related complications are far more expensive than costs for tools to identify and manage risks.

Case scenario: I had a gentleman who would bring me 3 data points every 1-2 months. Checking capillary blood "was cumbersome and painful". He purchased and used a flash glucose monitoring system and his first visit post use revealed hypoglycemia events occurring in the early AM undetected with fingersticks. He drove plow truck and would climb into his truck with lows "without awareness". The consequence of a hypoglycemia event would have far exceeded costs of one year of sensors. With the data his provider could modify his medical management using the details of the reports. Medication was adjusted and the results were seen quickly with the use of the flash monitoring data.

I invite you to please research the legitimacy of using the new glucose technology with the prevention of diabetes related complications.

Warm regards.

Lucy Gordon RN CDCES
600 St Johnsbury Rd
Littleton NH 03561

Phone: 603-444-9323 FAX: 603-259-7705

From: Nathan, Muriel H.
To: AHS - Medicaid Policy
Subject: Continuous glucose sensor reimbursement
Date: Tuesday, September 14, 2021 10:04:25 AM

To whom it may concern:

I believe it is a step backwards to not cover continuous glucose monitoring (CGM) for patients with type 1 or type 2 diabetes who use any insulin or sulfonylurea drug. As you know even minor hyperglycemia can lead to serious diabetic complications like neuropathy increasing the risk for falls, or retinopathy leading to loss of driving privileges. Thus doctors are using multiple drugs to achieve the A1c goal of <7% in many patients, and the use of any insulin or medication like Glyburide or Glipizide or Glimepiride can increase the risk for hypoglycemia. It is not a secret that many patients have hypoglycemic unawareness after a few years of disease, and COVID in the community and news has limited many face-to-face appointments and decreased episodes of regular care. Even the most conscientious patient only checks glucoses premeals and bedtime, leaving 8-10 hrs of no data about glucoses.

CGM is cost effective, as the sensors are worn for 7-14 days depending on brand, while chemstrips which cost $1 are used once. So in 10 days one gets about 40 glucoses by chemstrips at a cost of $40 ($1/value), while the sensor shows about 1,000 values for about $90-120 or 12 cents/value.

As the onus for patients with diabetes is to be in control >50-70% of the time depending on co-mo9rbidities and age and to have < 3% lows, this benchmark cannot be accomplished using fingersticks. The literature no longer accepts A1c as the gold standard for care, but rather time in range. This is because persons with A1c of 7% can have glucoses that range from 110-170 or the same average A1c of 7% with glucoses 70-210, and for the same A1c, the former range is much more desired.

Please allow our patients with diabetes to use CGM if they are on any insulin or drug that acts through insulin.

Dr. Muriel Nathan
University of Vermont
Vermont Regional Diabetes Center

From: Kelsey Sheahan, MD
To: AHS - Medicaid Policy
Subject: Continuous Glucose Monitoring Policies
Date: Tuesday, September 14, 2021 7:40:55 AM

To Whom It May Concern,

I am an Endocrinologist, a physician specialized in diabetes care, practicing at Northwestern Medical Center. I am writing in hopes that continuous glucose monitoring (CGM) coverage policy changes may be reconsidered. Diabetes care comprises the vast majority of my clinic, and CGM use is extremely beneficial for not just myself, but also for those on three injections of insulin, one injection daily, or even none at all. We have many non-insulin diabetes medications to use, but they affect glycemic control in different ways. For patients on one injection daily, if they are not meeting goals, I need to see glycemic trends to know whether to uptitrate insulin or the alternative non-insulin medications. Insulin titration can be beneficial, but also can be deadly, as hypoglycemia caused by insulin doses too high can have dire consequences. Additionally, CGM provides me a way to titrate insulin and other non-insulin medications remotely, as patients can upload their data to me, whereas otherwise there is no way to titrate these medications remotely. Patients also find the immediate feedback helpful and increases their engagement in improving glycemic control as well as their food choices and exercise habits. I believe CGM has benefited all of my patients and not only just those on insulin injections. In fact, a study by Wright et al., in Diabetes Spectrum, 2021 showed that CGM is associated with A1c reduction both in those on only one insulin injection daily, but also those on no insulin at all. I strongly urge you to reconsider the change in requirements for CGM therapy, and to at least grandfather those patients already on CGM therapy so we do not lose progress.

Thank you for your consideration,

Kelsey Sheahan, MD

September 29, 2021

Medicaid Policy Unit
280 State Drive, Center Building
Waterbury, VT 05671-1000
(via AHS.MedicaidPolicy@vermont.gov)

RE: Public Comment on Continuous Glucose Monitors (GCR 21-041)

Dear Medicaid Policy Unit Staff:

I am writing on behalf of the American Diabetes Association (ADA), the nation's largest voluntary health organization concerned with the health of people with diabetes. An estimated 34 million Americans and 43,000 Vermonters have diabetes, a chronic illness that requires continuing medical care and ongoing patient self-management to prevent acute complications and reduce the risk of long-term complications, such as blindness, amputation, kidney failure, heart attack, and stroke.

Advances in treatments, including continuous glucose monitoring (CGM), have been shown to be effective tools in diabetes management and the prevention of complications associated with the disease. Unfortunately, there continue to be gaps in access to CGM and other technologies among under-served populations, including – and perhaps most acutely – in the Medicaid population. ADA recommends you implement measures to broaden access for people with diabetes to these technologies that will enable them to better manage their diabetes, and which may result in fewer adverse health outcomes or even premature deaths.

ADA respectfully submits the below recommendations for your consideration. These recommendations broadly reflect our support for measures that will expand access to CGM technology for Green Mountain Care beneficiaries with diabetes.

Eliminating burdensome requirements in order to expand access to diabetes management technologies is vital to reducing disparities in utilization particularly among under-served people with diabetes. The ADA supports changes to the following proposed requirements.

> ***Eliminate the requirement of <u>multiple</u> daily insulin injections and replace "injection" with "administration"***
> Approaches to diabetes management and technology access should accommodate a variety of clinically appropriate strategies. ADA's 2021 *Standards of Medical Care in Diabetes* (*Standards*), which is updated annually by a committee of U.S. experts in diabetes care, provides that the use of professional CGM and/or intermittent real-time or intermittently scanned CGM can be helpful in identifying and correcting patterns of hyper-and hypoglycemia and improving A1C levels in people with diabetes on noninsulin as well as basal insulin regimens.[1] The ADA believes that requirements specifying <u>multiple</u> daily administrations of insulin, limit access to CGM for low-income and other patients who need it and recommend removal of this requirement. In accordance with this proposed change, ADA also recommends that "rapid/short-acting insulin" be replaced with "insulin" to

[1] American Diabetes Association: Standards of Medical Care in Diabetes 2021, Diabetes Care 44: Supp. 1, p.S88 (January 2021).

accommodate different clinical strategies. Furthermore, ADA supports the use of the word "administration" instead of "injection" in requirements related to insulin usage, as it permits users of inhaled insulin to benefit from CGM therapy.

Eliminate prior authorization barriers and make devices available through multiple channels to increase accessibility

Prior authorization requirements can present barriers that delay timely access to devices, medications, or therapies. These prior authorization barriers, which include step therapy protocols, frequently override what a provider believes to be in his or her patient's best clinical interest. ADA recommends that Green Mountain Care ensure that coverage and formulary decisions be based on clinical evidence and the direction of health care providers. Additionally, patients must be equipped with tools including a clear and timely appeals process for denials of coverage.

Broaden Channels of Access to CGM - ADA also recommends that CGM be made available through as many channels as possible including both mail-order and local pharmacies in order to increase access for the diverse population that can benefit from the devices.

Ensure patient- and provider-centered choices for CGM devices

We respectfully urge that Green Mountain Care take extra care to avoid making choices that would limit access for people with diabetes to CGM or any technology that those individuals and their doctors believe is most appropriate to manage their diabetes. ADA's 2021 *Standards* provide that the choice of technology should be individualized based on patient's needs, desires, skill level, and availability of devices. These are determinations that should be made by a patient in conjunction with their health care provider. Additionally, individuals who have been successfully using CGM should be able to continue to have access to that device across health care payers in order to avoid interruption in access that may result from the need for new training and education or lack of supplies and equipment. If coverage changes must occur, ADA recommends steps be taken to ensure a smooth transition process. At minimum, Green Mountain Care should adopt a transition period coupled with an exceptions process, enabling beneficiaries successfully using a CGM to continue to use that item and its associated supplies regardless of new limitations or exclusions.

The American Diabetes Association appreciates the opportunity to submit recommendations for your consideration and looks forward to working with you to implement measures aimed at increasing access to CGM for Green Mountain Care beneficiaries in Vermont.

Should you have any questions regarding these comments, please contact me at shabbe@diabetes.org.

Sincerely,

Stephen Habbe
Director, State Government Affairs