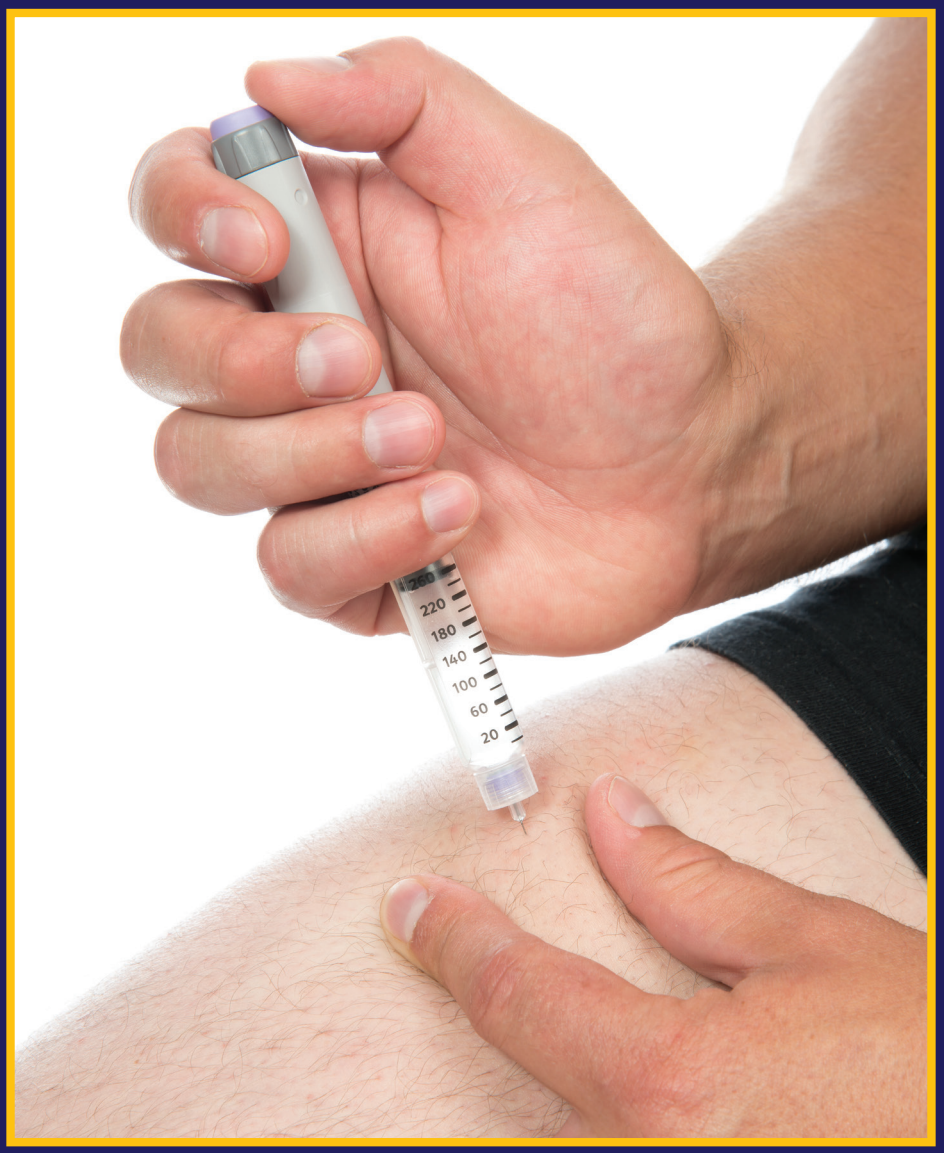
Using Continuous Glucose Monitoring to Improve Diabetes Treatment in Federal Medicine



U.S. Medicine
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VA Makes It Easier for Veterans to Get Continuous Glucose Monitors

By Annette M. Boyle

BOSTON—The VA's new prescribing guidance for continuous glucose monitors significantly expands the number of veterans with diabetes who are eligible for the devices. That could be good news for thousands of current and former servicemembers tired of pricking their fingers several times a day.

The VA cares for 1.6 million veterans with diabetes, which is about 25% of all the veterans enrolled in its healthcare system. Of those, a half-million are treated with insulin, according to Paul Conlin, MD, chief of medical services at the VA Boston Healthcare System. Most diabetes patients who use insulin check their blood glucose levels several times a day, a procedure that requires drawing blood via fingerstick.

Continuous glucose monitors offer a less painful and more timely alternative. The monitors are small devices that are typically worn on the abdomen or upper arm. They have a tiny sensor wire that stays under the skin to measure glucose concentrations in the body's interstitial fluid. Real-time CGMs measure glucose at regular intervals around the clock and have a transmitter connected to the sensor that sends the readings to a receiver or mobile device app where the user can see current glucose levels as well as trends. Real-time CGMs also provide alerts and alarms to let the wearer and, in some cases, caregivers, know if their blood glucose is headed in a dangerous direction.

Intermittently-scanned CGMs require the user to scan the sensor to see their glucose levels. They do not have alarms or alerts and typically require regular recalibration by checking results against fingerstick readings.

Continuous glucose monitors provide substantially more information for patients and providers to manage diabetes. "It has given us a snapshot into their lives that we have never seen before. They can get some of this data from doing fingersticks, but it's just a couple of points in the day, whereas with a continuous glucose monitor they have it literally at their fingertips whenever they want it," said Alicia Warnock, MD, former director of the Diabetes Institute at Walter Reed National Military Medical Center and U.S. Navy physician, and current chief operating officer of stability health in Worcester, MA.

New VA Rules

To qualify for a continuous glucose monitor, veterans with diabetes must require three or more insulin injections daily and four or more blood glucose level checks per day. In addition, veterans must have the skills to operate a CGM and agree to healthcare visits at least every six months to evaluate their use of the device and their diabetes.

Not everyone who meets those main criteria will qualify, however. The VA also requires a demonstrated risk of hypoglycemia, combined with trouble controlling their blood glucose levels, despite adherence to recommended therapy. Alternatively, individuals whose work environment poses a risk of harm if they experienced a hypoglycemic event and those who have difficulty self-monitoring blood glucose levels as a result of disability or disease may also

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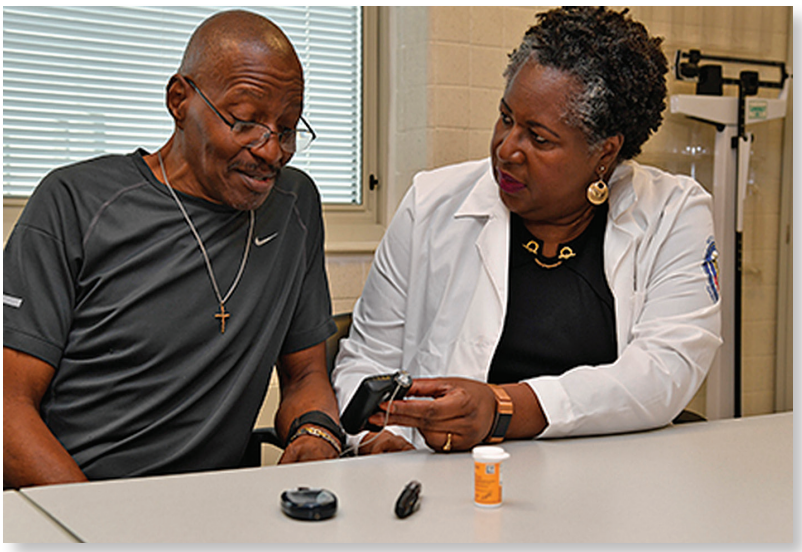
>
> —Dhiren Patel, PharmD

qualify for a CGM under the new program.

The expanded access aligns with the recommendations of the International Consensus of Use of Continuous Glucose Monitoring. Those say that "CGM should be considered in conjunction with HbA1c for glycemic status assessment and therapy adjustment in all patients with Type 1 diabetes and patients with Type 2 diabetes treated with intensive insulin therapy who are not achieving glucose targets, especially if the patient is experiencing problematic hypoglycemia."



The Ralph H. Johnson VA Medical Center Diabetes Self-Management Education Service at the main hospital in downtown Charleston, SC, has been awarded continued recognition from the American Diabetes Association. Here, diabetes educator Cheryl Pratt instructs veteran Dewayne Patterson how to use his insulin pump. —Photo by James Arrowood is on the VA website.

New Partnerships

In addition to covering use of continuous glucose monitors for a wider group of veterans, the VA has made it quicker and easier for veterans prescribed the devices to obtain them. Previously, prescriptions for Dexcom's G6 CGM were filled through the Durable Medical Equipment channel, which slowed access. Now, the entire monitoring system can be obtained through the pharmacy and, for qualifying veterans, at no cost.

The changes are already being noticed by veterans. "It's gone from taking months to get my first device ready to go to getting a refill in less than a week," Leaha Worthington, a Navy veteran in Temple, TX, told *U.S. Medicine*. "Before I had to get the transmitter from prosthetics and the sensor from the pharmacy and it took two months. Now I get the sensor pads and [sensor] that goes under the skin every 10 days. The system is definitely becoming more streamlined."

"Easier access to CGM at the pharmacy is a big win for veterans with diabetes. Research continues to show CGM should be the standard of care for any diabetes patient on intensive insulin therapy," said Dhiren Patel, PharmD, a clinical pharmacy specialist and certified diabetes educator at the VA Boston Healthcare System, associate professor of pharmacy practice at the Massachusetts College of Pharmacy and Health Sciences in Boston, and associate professor of Pharmacology at the Alpert Medical School of Brown University in Providence, RI. "Dexcom G6 has a number of highly beneficial features including predictive low alerts to help avoid dangerous low blood sugar events, time-in-range reports and remote monitoring capabilities that allow patients to share their glucose data in real time with up to 10 followers."

Other manufacturers of CGMs are also engaging with veterans to help them understand how to access the monitors and take control of their diabetes, as access for different systems may be through different channels. An implantable CGM, for instance, is procured through the prosthetics rather than pharmacy channels.

There are several options available, so veterans are likely to find a continuous glucose monitor that works for them and their lifestyle. "If patients are wondering if CGM is the right device for them, I would encourage them to become their own advocate for their health," said Warnock. "Read about it, find out as much as you can, but then come to your doctor with that information and ask them the question. Tell them what you've learned about CGM, what you don't know about CGM, and what struggles you're having taking care of your diabetes."

DoD Revises Requirements for Continuous Glucose Monitoring Use

By Annette M. Boyle

FORT BRAGG, NC—You can't join the service with diabetes, so why should the DoD care about monitoring blood sugar in those diagnosed with the disease?

Surprisingly, 2% to 3% of active duty servicemembers have diabetes. Not only can some diabetics stay in the service, they may even be deployed following medical board evaluation.

Some servicemembers will develop Type 1 diabetes, formerly known as juvenile diabetes. The cause of Type 1 diabetes remains unclear, but it likely has viral, environmental and genetic components. In Type 1, something triggers an attack on the pancreas by the immune system, wiping out the beta cells that make insulin.

"When a U.S. Army soldier is diagnosed with Type 1 diabetes, it is widely assumed that they will be found unfit for duty and their military career is over," according to researchers at Womack Army Medical Center at Fort Bragg, NC. "For highly motivated soldiers, current advanced technologies allow the possibility of not only retention on active duty, but military deployment."[1]

Most servicemembers, like 95% of other adults who develop diabetes, will have Type 2, which is less often career-ending. In Type 2 diabetes, the body develops resistance to insulin or fails to produce sufficient insulin to keep glucose levels normal.

According to the CENTCOM minimal standards of fitness for deployment, waivers are required for deployment of all Type 1 diabetics and Type 2 diabetics on insulin or with HbA1c over 7.0 mg/dl. Servicemembers with stable Type 2 diabetes that is managed with lifestyle modifications or oral medications only and who have HbA1c of 7.0 or less do not need a waiver as long as their calculated 10-year coronary heart disease risk is less than 15%.

A medical board evaluation might determine that an individual on insulin could stay in the service or even deploy, if their skill sets are unique and their disease well controlled. For those servicemembers, the need to maintain unit readiness creates an incentive to help them manage their blood glucose levels.

The Fort Bragg team and others have demonstrated that continuous glucose monitoring systems (CGMS) and rigorous training in diabetes management enabled retention of about 35% of servicemembers who developed Type 1 diabetes. Of those, nearly 25% successfully deployed.

Continuous glucose monitors help individuals with diabetes better manage their disease by providing readings of their blood glucose to a mobile app with updates every few minutes throughout the day and night. Where self-monitoring of blood glucose (SMBG) requires multiple finger pricks through the day to maintain good control, CGMs use a sensor that is inserted by an automatic applicator just below the skin so it can measure glucose in the interstitial fluid. The sensor transmits real-time readings to a receiver or compatible smart device. Custom alerts let people with diabetes know when their glucose levels are too high or too low.

Simplified Criteria

Until the beginning of this year, continuous glucose monitoring systems were available only for servicemembers with Type 1 diabetes who met strict criteria for poorly controlled diabetes. At the time, physicians had to extensively document significant issues caused by the individuals hyper- or hypoglycemia. In most cases, the devices could only be used intermittently with use restricted to three days at a time and not more than six times in year.

The current policy expands "coverage of continuous glucose monitoring systems to therapeutic devices and to modernize the indications for which [continuous glucose monitoring systems] CGMS may be cost shared to ensure they align with best clinical practice,"

according to a Defense Health Agency (DHA) report to the Senate Armed Services Committees. Therapeutic devices replace fingerstick blood glucose monitoring; those that require fingersticks are considered adjunctive devices.

"DHA estimates that the cost of adding CGMS for Type 2 diabetes will be approximately $8 million over 5 years," according to the report. "This estimate does not take into consideration the decrease in health care expenditures that may result from improved glycemic control."

The cost savings could be substantial given the risks associated with poorly controlled diabetes. "Diabetics using tools like CGMS have fewer complications and better control over their disease," the report noted. "Poorly controlled diabetes, regardless of the Type (e.g., Type 1 or Type 2), can result in significant morbidity, to include weakness and dizziness, tremors, palpitations, delirium, confusion, seizures, coma, increased thirst, increased urination, weight loss, lethargy, and secondary conditions such as atherosclerosis, vision problems or blindness, kidney-related complications, and nerve damage."

Some servicemembers are able to remain on active duty with diabetes. In this 2007 photo, a soldier serving in Kuwait checks his blood sugar manually.
—Army photo by Spc. Wesley Landrum of the 50th Public Affairs Detachment

Under the updated guidance, TRICARE covers continuous glucose monitoring for all Types of diabetes and requires much less onerous documentation for servicemembers, their dependents and retirees. The new policy includes all continuous glucose monitoring devices approved by the U.S. Food and Drug Administration.

The prescribing physician must document that the individual has had difficulty achieving diabetic control despite at least three daily insulin injections or insulin pump therapy with blood glucose self-testing at least four times a day and completion of a diabetic education program. The patient must also have seen a provider for diabetes control within the previous six months.

To qualify for the devices, patients must have at least one of the following:

- HBA1c levels greater than 7.0% or less than 4.0%
- a history of significant, unexplained fluctuations in daily glucose levels prior to meals
- early morning fasting hyperglycemia
- a history of severe glycemic fluctuations
- hypoglycemic unawareness, nocturnal hypoglycemia or a history of unexplained, severe hypoglycemic events with blood glucose levels below 50 mg/dl
- recurrent episodes of ketoacidosis or hospitalizations for uncontrolled glucose levels
- pregnancy with poorly controlled diabetes or gestational diabetes.

[1] Choi YS, Cucura J. US Army Soldiers With Type 1 Diabetes Mellitus. *J Diabetes Sci Technol.* 2018;12(4):854-858. doi:10.1177/1932296818767700

CGM Use Protects Both Hospitalized COVID-19 Patients, Healthcare Workers

By Annette M. Boyle

OMAHA, NE—COVID-19 and diabetes have proven to be a deadly combination. For patients infected with the novel coronavirus, diabetes more than doubles the odds of death. For healthcare workers, the need to closely monitor glucose levels and administer insulin or other medications creates additional exposure to a virulent pathogen.

Multiple studies have found that 20% to 35% of COVID-19 patients in intensive care have diabetes. To complicate issues, uncontrolled hyperglycemia is associated with longer hospital stays, while many of the drugs used to treat COVID-19 can increase blood sugar levels. Further, research indicates that the novel coronavirus can also trigger new onset diabetes.

"Much has been written about the treatment of patients with COVID-19 in general, but little guidance has been provided to clinicians on how to treat their patients with diabetes," said Andjela Drincic, MD, professor in the department of Internal Medicine, Division of Division of Diabetes, Endocrine and Metabolism at the University of Nebraska in Omaha. "And yet, hyperglycemia in this population is rampant and difficult to treat."

Drincic and colleagues from the National Institutes of Health and major academic medical centers across the country recently published guidelines that outline a pragmatic approach to management of patients with high blood glucose levels who are hospitalized with COVID-19.[1]

Standard recommendations for managing hyperglycemic hospitalized patients call for at least four capillary blood glucose measurements per day using fingersticks, portable glucose monitors for patients receiving insulin injections and hourly tests for those on IV insulin. Hospitals experiencing a surge of patients with the coronavirus often lack the personnel and protective equipment needed to safely maintain such frequent monitoring at bedside.

"These healthcare providers are at risk for contracting COVID-19, and while glycemic management in the hospital improves patient outcomes, it also intensifies the amount of time with direct patient contact," noted lead author Mary T. Korytkowski, MD, of the University of Pittsburgh School of Medicine in Pittsburgh.

Yet, reducing the number of blood glucose checks can be particularly dangerous in the current environment. "It is important to note that insulin requirements can vary on a daily, if not hourly basis, in patients with critical COVID-19 infections where there is variability in insulin sensitivity over the course of the illness," the authors wrote. Wide fluctuations in insulin requirements in these patients can be exacerbated by medications, especially corticosteroids and hydroxychloroquine, and impaired kidney function prior to or as a result of their coronavirus infection.

Generally, patients who are taking noninsulin medications to manage their diabetes at the time of admission should be switched to insulin and patients with newly recognized hyperglycemia should initiate insulin to avoid a range of adverse effects. In some cases, the dipeptidyl peptidase 4 inhibitors (DPP4i) sitagliptin and linagliptin could be considered in patients with mild, recovering cases.

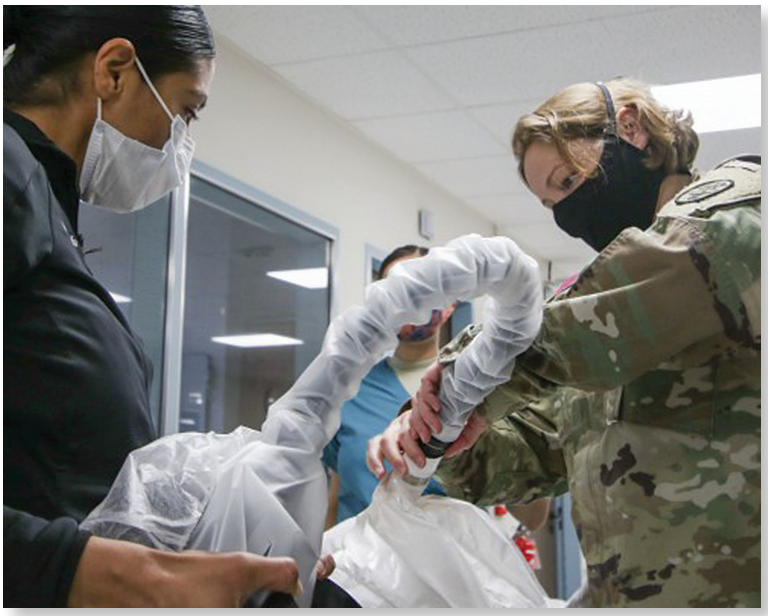
Continuous Glucose Monitoring

With insulin advised for most COVID-19 patients with diabetes, how can hard-hit hospitals manage appropriate monitoring? The authors note that some patients may be able to continue self-monitoring blood glucose levels, reducing the burden of healthcare workers. This group could include noncritically ill patients comfortable with performing regular fingerpricks and using their own or a hospital-provided blood glucose meter as well as those who enter the hospital with their own continuous glucose monitoring (CGM) devices.

In April, the U.S. Food and Drug Administration announced that it would not object to in-hospital use of continuous glucose monitors to manage glycemic issues in COVID-19 patients, which had previously been cleared for use only in ambulatory and research settings.

The FDA decision has enabled many hospitals around the country to use the two CGM devices that do not require regular calibration against capillary blood glucose measures and enable remote monitoring of blood glucose data for up to 14 days. The manufacturers of both devices have made their CGMs available at a reduced cost during the pandemic.

Scripps Health in San Diego is one system that chose to use the devices. "By taking advantage of the opportunity allowed by the FDA, we are bringing down barriers that normally would have impeded the broader use of this technology in hospitals and, instead, rapidly yet safely bringing it to the bedside where it will benefit both patients and staff members," Scripps Whittier Diabetes Institute lead research scientist Addie Fortmann, PhD, said.



Medical personnel at Landstuhl Regional Medical Center in Germany familiarize themselves with the Powered Air-Purifying Respirator System, to increase safety while caring for COVID-19 patients. Devices like continuous glucose monitors help limit contact.
—Army photo by Marcy Sanchez

Scripps Whittier has been using CGM in a clinical study for five years. Preliminary results demonstrated that the devices were safe and feasible to use in a hospital environment and were associated with trends toward better glycemic control.

Rush University Medical Center in Chicago also reported good results in its early use of CGM during the pandemic. Rasa Kazlauskaite, MD, MS, director of the diabetes technology program at Rush University and associate professor at Rush Medical College, observed that the devices not only reduced demands on nursing staff, they improved patient safety by providing a fuller picture of a blood glucose levels over the course of a day. The greater frequency of measurements reduced the risk of undetected hypoglycemic or hyperglycemic episodes.

Francisco J. Pasquel, MD, MPH, a physician at Emory University Hospital in Atlanta, noted that the devices were particularly valuable for intensive care patients who must maintain glucose levels in a narrow range while on IV insulin. In this setting and others where CGM indicates the need for adjustment in insulin doses or glucose levels are rapidly changing, the manufacturers recommend validating results with point of care capillary blood glucose measurements.

Pasquel, who co-authored an article on implementation of CGM in hospitals during the pandemic with colleagues at Emory and other leading medical schools as well as physicians at the Baltimore and Atlanta VAMCs, also noted that CGM would be useful for patients on other floors as well, including patients on steroids and those who require medical nutrition therapy.[2]

[1] Korytkowski M, Antinori-Lent K, Drincic A, et al. A Pragmatic Approach to Inpatient Diabetes Management during the COVID-19 Pandemic. *J Clin Endocrinol Metab*. 2020;105(9):dgaa342. doi:10.1210/clinem/dgaa342

[2] Galindo RJ, Aleppo G, Klonoff DC, et al. Implementation of Continuous Glucose Monitoring in the Hospital: Emergent Considerations for Remote Glucose Monitoring During the COVID-19 Pandemic. *Journal of Diabetes Science and Technology*. 2020;14(4):822-832. doi:10.1177/1932296820932903

FINGERSTICK AFTER WAKING UP.

FINGERSTICK BEFORE BREAKFAST.

FINGERSTICK AFTER BREAKFAST.

FINGERSTICK BEFORE A WORKOUT.

FINGERSTICK AFTER A LONG MEETING.

FINGERSTICK BEFORE LUNCH.

FINGERSTICK AFTER LUNCH.

FINGERSTICK DURING A BREAK.

FINGERSTICK AFTER AN INTERVIEW.

FINGERSTICK AFTER A GAME.

FINGERSTICK BEFORE DINNER.

FINGERSTICK AFTER DINNER.

FINGERSTICK AFTER A SHOWER.

FINGERSTICK BEFORE DESSERT.

FINGERSTICK AFTER DESSERT.

FINGERSTICK AFTER A DATE.

FINGERSTICK BEFORE DRIVING.

FINGERSTICK BEFORE A FLIGHT.

FINGERSTICK BEFORE BED.

FINGERSTICK IN THE MIDDLE OF THE NIGHT.

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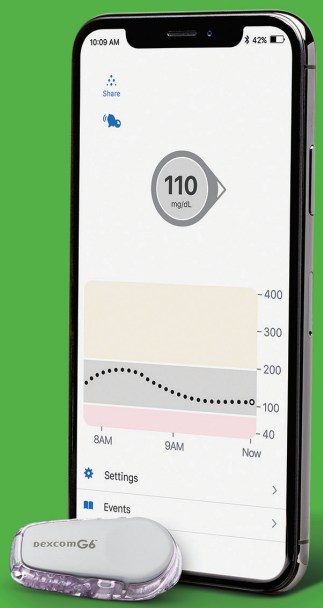
Now without fingersticks.*



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*If your glucose alerts and readings from the G6 do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions.

†For a list of compatible devices, visit dexcom.com/compatibility.
[1]Beck, RW. JAMA. 2017; 317(4); 371-378. [2]Welsh, J.B. Diabetes Technol Ther. 2019; 21(3)

BRIEF SAFETY STATEMENT Available by prescription only. Failure to use the Dexcom G6 Continuous Glucose Monitoring System (G6) and its components according to the instructions for use provided with your device and available at dexcom.com/safety-information and to properly consider all indications, contraindications, warnings, precautions, and cautions in those instructions for use may result in you missing a severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) occurrence and/or making a treatment decision that may result in injury. If your glucose alerts and readings from the G6 do not match symptoms, use a blood glucose meter to make diabetes treatment decisions. Seek medical advice and attention when appropriate, including for any medical emergency.

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