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# Make room for continuous glucose monitoring in type 2 diabetes management

Here's how the various devices can be used to reach an individualized target of glycemic control and what reimbursement to expect from insurers.

## **PRACTICE RECOMMENDATIONS**

- › *Initiate continuous glucose monitoring early in the disease process, based on a patient's needs or preferences.* (C)
- › *Interpret a continuous glucose monitor (CGM) report with the understanding that time within target range is the most important factor to evaluate. Minimizing or eliminating time below range is of paramount importance.* (B)
- › *Advise patients who use a CGM to continue to have access to a glucometer and instruct them on appropriate times when such confirmation might be necessary.* (B)

### Strength of recommendation (SOR)

- (A) Good-quality patient-oriented evidence
- (B) Inconsistent or limited-quality patient-oriented evidence
- (C) Consensus, usual practice, opinion, disease-oriented evidence, case series

**A**1C has been used to estimate 3-month glycemic control in patients with diabetes. However, A1C monitoring alone does not provide insight into daily glycemic variation, which is valuable in clinical management because tight glycemic control (defined as A1C < 7.0%) has been shown to reduce the risk of microvascular complications. Prior to the approval of glucagon-like peptide-1 receptor agonists and sodium-glucose co-transporter 2 inhibitors by the US Food and Drug Administration for the treatment of type 2 diabetes (T2D), reduction in the risk of macrovascular complications (aside from nonfatal myocardial infarction) was more difficult to achieve than it is now; some patients had a *worse* outcome with overly aggressive glycemic control.<sup>1</sup>

Previously, the use of a continuous glucose monitor (CGM) was limited to patients with type 1 diabetes who required basal and bolus insulin. However, technological advances have led to more patient-friendly and affordable devices, making CGMs more available. As such, the American Diabetes Association (ADA), in its 2022 *Standards of Medical Care in Diabetes*, recommends that clinicians offer continuous glucose monitoring to adults with T2D who require multiple daily injections, and based on a given patient's ability, preferences, and needs.<sup>2</sup>

In this article, we discuss, first, the intricacies of CGMs and, second, what the evidence says about their use so that physicians can confidently recommend, and educate patients on, effective utilization of CGMs to obtain an individualized target of glycemic control.

## **Continuous glucose monitoring: A glossary**

CGMs are characterized by who possesses the device and how data are recorded. This review is *not* about professional CGMs, which are owned by the health care provider and consist of

a sensor that is applied in the clinic and returned to clinic for downloading of data<sup>1</sup>; rather, we focus on the novel category of non-professional, or personal, CGMs.

■ **Three words to remember.** Every CGM has 3 common components:

- The *reader* (also known as a *receiver*) is a handheld device that allows a patient to scan a sensor (see definition below) and instantaneously collect a glucose reading. The patient can use a standalone reader; a smartphone or other smart device with an associated app that serves as a reader; or both.
- A *sensor* is inserted subcutaneously to measure interstitial glucose. The lifespan of a sensor is 10 to 14 days.
- A *transmitter* relays information from the sensor to the reader.

### The technology behind a CGM

CGM sensors measure interstitial glucose by means of a chemical reaction involving glucose oxidase and an oxidation-reduction cofactor, measuring the generation of hydrogen peroxide.<sup>3</sup> Interstitial glucose readings lag behind plasma blood glucose readings by 2 to 21 minutes.<sup>4,5</sup> Although this lag time is often not clinically significant, situations such as aerobic exercise and a rapidly changing glucose level might warrant confirmation by means of fingerstick measurement.<sup>5</sup> It is common for CGM readings to vary slightly from venipuncture or fingerstick glucose readings.

### What CGMs are available to your patients?

■ **Intermittently scanned CGMs** (isCGMs) measure the glucose level continuously; the patient must scan a sensor to display and record the glucose level.<sup>6</sup> Prolonged periods without scanning result in gaps in glycemic data.<sup>7,8</sup>

Two isCGM systems are available: the FreeStyle Libre 14 day and the FreeStyle Libre 2 (both from Abbott).<sup>a</sup> Both consist of a reader and a disposable sensor, applied to the back of the arm, that is worn for 14 days. If the patient has a compatible smartphone or other smart device, the reader can be replaced by the smart device with the downloaded

FreeStyle Libre or FreeStyle Libre 2 app.

To activate a new sensor, the patient applies the sensor, then scans it. Once activated, scanning the sensor provides the current glucose reading and recalls the last 8 hours of data. In addition to providing an instantaneous glucose reading, the display also provides a trend arrow indicating the direction and degree to which the glucose level is changing (TABLE 1<sup>10,14,15</sup>). This feature helps patients avoid hypoglycemic episodes by allowing them to preemptively correct if the arrow indicates a rapidly declining glucose level.

For the first 12 hours after a new sensor is activated, and when a glucose reading is < 70 mg/dL, patients should be instructed to avoid making treatment decisions and encouraged to utilize fingerstick glucose readings. FreeStyle Libre 14 day does *not* allow a glucose level alarm to be set; the system cannot detect these events without scanning the sensor.<sup>10</sup> Bluetooth connectivity does allow FreeStyle Libre 2 users to set a glucose alarm if the reader or smart device is within 20 feet of the sensor. A default alarm is set to activate at 70 mg/dL (“low”) and 240 mg/dL (“high”); low and high alarm settings are also customizable. Because both FreeStyle Libre devices store 8 hours of data, patients must scan the sensor every 8 hours for a comprehensive glycemic report.<sup>14</sup>

FreeStyle Libre CGMs allow patients to add therapy notes, including time and amount of insulin administered and carbohydrates ingested. Readers for both devices function as a glucometer that is compatible with Abbott FreeStyle Precision Neo test strips.

■ **Real-time CGMs** (rtCGMs) measure and display glucose levels continuously for the duration of the life of the sensor, without the need to scan. Three rtCGM systems are available: Dexcom G6, Medtronic Guardian 3, and Senseonics Eversense E3.

*Dexcom G6* is the first Dexcom CGM that

<sup>a</sup> The US Food and Drug Administration cleared a new Abbott CGM, FreeStyle Libre 3, earlier this year; however, the device is not yet available for purchase. With advances in monitoring technology, several other manufacturers also anticipate introducing novel CGMs. (See “Continuous glucose monitors: The next generation,” on page 390.<sup>9-13</sup>)

➤ **Continuous glucose monitor readings often vary slightly from venipuncture or fingerstick glucose readings.**

TABLE 1

## What do trend arrows signify on FreeStyle Libre and Dexcom personal CGMs?<sup>10,14,15</sup>

Trend arrow	Meaning	Change in glucose level
↔	Steady or changing slowly	< 1 mg/dL/min
↗ or ↘	Slowly rising or falling	1-2 mg/dL/min
↑ or ↓	Quickly rising or falling	> 2 mg/dL/min

CGMs, continuous glucose monitors.

➤ Continuous glucose monitor (CGM) manufacturers recommend that patients have access to a fingerstick glucometer to verify CGM readings when concerns about accuracy exist.

does not require fingerstick calibration and the only rtCGM available in the United States that does not require patient calibration. This system comprises a single-use sensor replaced every 10 days; a transmitter that is transferred to each new sensor and replaced every 3 months; and an optional receiver that can be omitted if the patient prefers to utilize a smart device.

Dexcom G6 never requires a patient to scan a sensor. Instead, the receiver (or smart device) utilizes Bluetooth technology to obtain blood glucose readings if it is positioned within 20 feet of the transmitter. Patients can set both hypoglycemic and hyperglycemic alarms to predict events within 20 minutes. Similar to the functionality of the FreeStyle Libre systems, Dexcom G6 provides the opportunity to log lifestyle events, including insulin dosing, carbohydrate ingestion, exercise, and sick days.<sup>15</sup>

*Medtronic Guardian 3* comprises the multi-use Guardian Connect Transmitter that is replaced annually and a single-use Guardian Sensor that is replaced every 7 days. Guardian 3 requires twice-daily fingerstick glucose calibration, which reduces the convenience of a CGM.

Guardian 3 allows the user to set alarm levels, providing predictive alerts 10 to 60 minutes before set glucose levels are reached. Patients must utilize a smart device to connect through Bluetooth to the CareLink Connect app and remain within 20 feet of the transmitter to provide continuous glucose readings. The CareLink Connect app allows patients to document exercise, calibration of fingerstick readings, meals, and insulin administration.<sup>16</sup>

*Senseonics Eversense E3* consists of a 3.5 mm × 18.3 mm sensor inserted sub-

cutaneously in the upper arm once every 180 days; a removable transmitter that attaches to an adhesive patch placed over the sensor; and a smart device with the Eversense app. The transmitter has a 1-year rechargeable battery and provides the patient with on-body vibration alerts even when they are not near their smart device.

The Eversense E3 transmitter can be removed and reapplied without affecting the life of the sensor; however, no glucose data will be collected during this time. Once the transmitter is reapplied, it takes 10 minutes for the sensor to begin communicating with the transmitter. Eversense provides predictive alerts as long as 30 minutes before hyperglycemic or hypoglycemic events. The device requires twice-daily fingerstick calibrations.<sup>17</sup>

A comparison of the specifications and capabilities of the personal CGMs discussed here is provided in TABLE 2.<sup>10,14-17</sup>

### The evidence, reviewed

Clinical outcomes evidence with CGMs in patients with T2D is sparse. Most studies that support improved clinical outcomes enrolled patients with type 1 diabetes who were treated with intensive insulin regimens. Many studies utilized rtCGMs that are capable of incorporating a hypoglycemic alarm, and results might not be generalizable to isCGMs.<sup>18,19</sup> In this article, we review only the continuous glucose monitoring literature in which subjects had T2D.

### Evidence for isCGMs

■ The REPLACE trial compared outcomes in patients with T2D who used an isCGM vs those who self-monitored blood glucose

TABLE 2

Personal CGMs, compared<sup>10,14-17</sup>

Specifications and capabilities	FreeStyle Libre 14 day (Abbott) <sup>10</sup>	FreeStyle Libre 2 (Abbott) <sup>14</sup>	Dexcom G6 (Dexcom) <sup>15</sup>	Guardian Connect 3 (Medtronic) <sup>16</sup>	Eversense E3 (Senseonics) <sup>17</sup>
Type	Intermittently scanned CGM		Real-time CGM		
Approved age of use	≥ 18 y	≥ 4 y	≥ 2 y	14-75 y	≥ 18 y
Blood glucose range	40-500 mg/dL	40-400 mg/dL	40-400 mg/dL		
Need to scan sensor	At least every 8 h		No		
Frequency of stored glucose level	Every 15 min		Every 5 min		
Overall MARD	9.4%	9.2%	9.8%	9.1% <sup>a</sup>	8.5%
Sensor placement	Back of upper arm		Abdomen	Abdomen or back of upper arm	Subcutaneous implant in upper arm
Patient calibration required	No		No	Every 12 h <sup>b</sup>	Every 12 h
Warm-up period	60 min		120 min	As long as 120 min	24 h <sup>c</sup>
Sensor life	14 d		10 d	7 d	180 d
Smart-device requirement	Smart device or supplied reader		Smart device or receiver	Smart device	
Glucose alerts	No		Yes		
Can be integrated with insulin pump	No		Yes		
Interfering substances	> 500 mg vitamin C: falsely <i>increases</i> scanned glucose level Salicylic acid: falsely <i>decreases</i> scanned glucose level	> 500 mg vitamin C: falsely <i>increases</i> scanned glucose level	Hydroxyurea: falsely <i>increases</i> scanned glucose level	Acetaminophen: falsely <i>increases</i> scanned glucose level	Intravenous mannitol or sorbitol: falsely <i>increases</i> scanned glucose level
Waterproof	1 meter; 30 min		2.4 meters; 24 h	2.4 meters; 30 min	1 meter; 30 min
Data retrieval platform for clinic	LibreView		Dexcom Clarity	CareLink	Eversense Data Management System (DMS) Pro
Data sharing platform for family and friends	LibreLinkUp (≤ 20 people)		Dexcom Follow (≤ 10 people)	CareLink Connect (≤ 5 people)	Eversense NOW (≤ 5 people)
Patient smartphone app requirement	Reader: N/A Smartphone: LibreLink	Reader: N/A Smartphone: Libre 2	Dexcom Clarity	Guardian Connect	Eversense

CGM, continuous glucose monitor; MARD, mean absolute relative difference; N/A, not applicable. (For more on MARD, see page 389.)

<sup>a</sup>When calibrated every 12 h; MARD is slightly better (8.68%) when calibrated 3 or 4 times a day.

<sup>b</sup>A new sensor requires as long as 2 h to warm up; then needs to be calibrated immediately; then needs to be calibrated 6 h after initial calibration; and then needs to be calibrated every 12 h for the duration of the sensor. The more regularly the sensor is calibrated, the more improved is its accuracy.

<sup>c</sup>ie, 24 h after the initial sensor placement and 10 min each time the transmitter is removed and replaced.

➤  
A sensor that becomes dislodged can malfunction or lose accuracy. Patients should not try to reapply the sensor; they should remove and discard it and apply a new one.

(SMBG); both groups were being treated with intensive insulin regimens. Both groups had similar glucose reductions, but the time in the hypoglycemic range (see “Clinical targets,” in the text that follows) was significantly shorter in the isCGM group.<sup>20</sup>

■ **A randomized controlled trial (RCT)** that compared intermittently scanned continuous glucose monitoring and SMBG in patients with T2D who received multiple doses of insulin daily demonstrated a significant A1C reduction of 0.82% with an isCGM and 0.33% with SMBG, with no difference in the rate of hypoglycemic events, over 10 weeks.<sup>21</sup>

■ **Chart review.** Data extracted from chart reviews in Austria, France, and Germany demonstrated a mean improvement in A1C of 0.9% among patients when using a CGM after using SMBG previously.<sup>22</sup>

■ **A retrospective review** of patients with T2D who were not taking bolus insulin and who used a CGM had a reduction in A1C from 10.1% to 8.6% over 60 to 300 days.<sup>23</sup>

#### Evidence for rtCGMs

■ **The DIAMOND study** included a subset of patients with T2D who used an rtCGM and were compared to a subset who received usual care. The primary outcome was the change in A1C. A 0.3% greater reduction was observed in the CGM group at 24 weeks. There was no difference in hypoglycemic events between the 2 groups; there were few events in either group.<sup>24</sup>

■ **An RCT** demonstrated a similar reduction in A1C in rtCGM users and in nonusers over 1 year.<sup>25</sup> However, patients who used the rtCGM by protocol demonstrated the greatest reduction in A1C. The CGM utilized in this trial required regular fingerstick calibration, which likely led to poorer adherence to protocol than would have been the case had the trial utilized a CGM that did not require calibration.

■ **A prospective trial** demonstrated that utilization of an rtCGM only 3 days per month for 3 consecutive months was associated with (1) significant improvement in A1C (a decrease of 1.1% in the CGM group, compared to a decrease of 0.4% in the SMBG group) and (2) numerous lifestyle modifications, includ-

ing reduction in total caloric intake, weight loss, decreased body mass index, and an increase in total weekly exercise.<sup>26</sup> This trial demonstrated that CGMs might be beneficial earlier in the course of disease by reinforcing lifestyle changes.

■ **The MOBILE trial** demonstrated that use of an rtCGM reduced baseline A1C from 9.1% to 8.0% in the CGM group, compared to 9.0% to 8.4% in the non-CGM group.<sup>27</sup>

## Practical utilization of CGMs

### Patient education

Detailed patient education resources—for initial setup, sensor application, methods to ensure appropriate sensor adhesion, and app and platform assistance—are available on each manufacturer’s website.

### Clinical targets

In 2019, the Advanced Technologies & Treatments for Diabetes Congress determined that what is known as the *time in range* metric yields the most practical data to help clinicians manage glycemic control.<sup>28</sup> The time in range metric comprises:

- time in the target glucose range (TIR)
- time below the target glucose range (TBR)
- time above the target glucose range (TAR).

TIR glucose ranges are modifiable and based on the A1C goal. For example, if the A1C goal is < 7.0%, the TIR glucose range is 70-180 mg/dL. If a patient maintains TIR > 70% for 3 months, the measured A1C will correlate well with the goal. Each 10% fluctuation in TIR from the goal of 70% corresponds to a difference of approximately 0.5% in A1C. Therefore, TIR of approximately 50% predicts an A1C of 8.0%.<sup>28</sup>

A retrospective review of 1440 patients with CGM data demonstrated that progression of retinopathy and development of microalbuminuria increased 64% and 40%, respectively, over 10 years for each 10% reduction in TIR—highlighting the importance of TIR and consistent glycemic control.<sup>29</sup> Importantly, the CGM sensor must be active

TABLE 3

Medicare Part B eligibility criteria and quantity limits for CGMs<sup>32</sup>

Eligibility criteria <sup>a</sup>			
1. Patient has a diagnosis of diabetes <i>and</i>			
2. Patient is being treated with insulin, with $\geq 3$ daily insulin injections or continuous subcutaneous insulin infusion <i>and</i>			
3. Patient's insulin treatment regimen requires frequent adjustment, based on blood glucose monitoring or current CGM testing <i>and</i>			
4. Patient has had an in-person visit with their provider in $< 6$ mo <i>before</i> ordering the CGM, to confirm that eligibility criteria 1-3 have been met <i>and</i>			
5. Patient is seen by their provider <i>at least</i> every 6 mo to assess adherence to continuous glucose monitoring and the diabetes treatment plan			
Quantity limits			
CGM	Reader	Sensor	Transmitter
Freestyle Libre 14 day	1-3 y	2/28 d; 6/84 d	N/A
Freestyle Libre 2			
Dexcom G6		3/30 d; 9/90 d	1/90 d

CGM, continuous glucose monitor; N/A, not applicable.

<sup>a</sup> CGMs can be covered under the durable medical equipment benefit once all listed eligibility criteria are met.

$\geq 70\%$  of the wearable time to provide adequate TIR data.<sup>30</sup>

### Concerns about accuracy

There is no universally accepted standard for determining the accuracy of a CGM; however, the mean absolute relative difference (MARD) is the most common statistic referenced. MARD is calculated as the average of the absolute error between all CGM values and matched reference values that are usually obtained from SMBG.<sup>31</sup> The lower the MARD percentage, the better the accuracy of the CGM. A MARD of  $\leq 10\%$  is considered acceptable for making therapeutic decisions.<sup>30</sup>

Package labeling for all CGMs recommends that patients have access to a fingerstick glucometer to verify CGM readings when concerns about accuracy exist. If a sensor becomes dislodged, it can malfunction or lose accuracy. Patients should not try to re-apply the sensor; instead, they should remove and discard the sensor and apply a new one. TABLE 2<sup>10,14-17</sup> compares MARD for CGMs and lists substances that might affect the accuracy of a CGM.

### Patient-provider data-sharing platforms

■ **FreeStyle Libre and Libre 2.** Providers cre-

ate a LibreView Practice ID at [www.LibreView.com](http://www.LibreView.com). Patient data-sharing depends on whether they are using a smart device, a reader, or both. Patients can utilize both the smart device and the reader but must upload data from the reader at regular intervals to provide a comprehensive report that will merge data from the smart device (ie, data that have been uploaded automatically) and the reader.<sup>7</sup>

■ **Dexcom G6.** Clinicians create a Dexcom CLARITY account at <https://clarity.dexcom.com> and add patients to a practice list or gain access to a share code generated by the patient. Patients must download the Dexcom CLARITY app to create an account; once the account is established, readings will be transmitted to the clinic automatically.<sup>15</sup> A patient who is utilizing a nonsmart-device reader must upload data manually to their web-based CLARITY account.

### Family and caregiver access

Beyond sharing CGM data with clinic staff, an important feature available with FreeStyle Libre and Dexcom systems is the ability to share data with friends and caregivers. The relevant platforms and apps are listed in TABLE 2.<sup>10,14-17</sup>

CONTINUED

## Continuous glucose monitors: The next generation<sup>9-13</sup>

Expect new continuous glucose monitoring devices to be introduced to US and European health care markets in the near future.

**FreeStyle Libre 3** (Abbott) was cleared by the US Food and Drug Administration in May 2022, although it is not yet available for purchase. The manufacturer promotes the device as having the smallest sensor of any continuous glucose monitor (the diameter and thickness of 2 stacked pennies); improved mean absolute relative difference; the ability to provide real-time glucose level readings; and 50% greater range of Bluetooth connectivity (about 10 extra feet).<sup>9,10</sup>

**Dexcom G7** (Dexcom) has a sensor that is 60% smaller than the Dexcom G6 sensor and a 30-minute warm-up time, compared to 120 minutes for the G6.<sup>11</sup> The device has received European Union CE mark approval.

**Guardian 4 Sensor** (Medtronic) does not require fingerstick calibration. The device has also received European Union CE mark approval<sup>12</sup> but is available only for investigational use in the United States.

**Eversense XL** technology is similar to that of the Eversense E3, including a 180-day sensor.<sup>13</sup> The device, which has received European Union CE mark approval, includes a removable smart transmitter.

### Insurance coverage, cost, and accessibility

Medicare Part B has established criteria by which patients with T2D qualify for a CGM (TABLE 3<sup>32</sup>). A Medicare patient who has been determined to be eligible is responsible for 20% of the out-of-pocket expense of the CGM and supplies once their deductible is met. Once Medicare covers a CGM, the patient is no longer able to obtain fingerstick glucose supplies through Medicare; they must pay the cash price for any fingerstick supplies that are determined to be necessary.<sup>32</sup>

Patients with private insurance can obtain CGM supplies through their preferred pharmacy when the order is written as a prescription (the same as for fingerstick glucometers). That is *not* the case for patients with Medicare because not all US distributors and pharmacies are contracted to bill Medicare Part B for CGM supplies. A list of

distributors and eligible pharmacies can be found on each manufacturer's website.

### Risk-benefit analysis

CGMs are associated with few risks overall. The predominant adverse effect is contact dermatitis; the prevalence of CGM-associated contact dermatitis is difficult to quantify and differs from device to device.

■ **FreeStyle Libre.** In a retrospective review of records of patients with diabetes, researchers determined that a cutaneous adverse event occurred in approximately 5.5% of 1036 patients who utilized a FreeStyle Libre sensor.<sup>33</sup> Of that percentage, 3.8% of dermatitis cases were determined to be allergic in nature and related to isobornyl acrylate (IBOA), a chemical constituent of the sensor's adhesive that is not used in the FreeStyle Libre 2. Among patients who wore a sensor and developed allergic contact dermatitis, interventions such as a barrier film were of limited utility in alleviating or preventing further cutaneous eruption.<sup>33</sup>

■ **Dexcom G6.** The prevalence of Dexcom G6-associated allergic contact dermatitis is more difficult to ascertain (the IBOA adhesive was replaced in October 2019) but has been reported to be less common than with FreeStyle Libre,<sup>34</sup> a finding that corroborates our anecdotal clinical experience. Although Dexcom sensors no longer contain IBOA, cases of allergic contact dermatitis are still reported.<sup>35</sup> We propose that the lower incidence of cutaneous reactions associated with the Dexcom G6 sensor might be due to the absence of IBOA and shorter contact time with skin.

In general, patients should be counseled to rotate the location of the sensor and to use only specific barrier products that are recommended on each manufacturer's website. The use of other barriers that are not specifically recommended might compromise the accuracy of the sensor.

### Summing up

As CGM technology improves, it is likely that more and more of your patients will utilize one of these devices. The value of CGMs has been documented, but any endorsement of their use is qualified:

- Data from many older RCTs of patients with T2D who utilize a CGM did *not* demonstrate a significant reduction in A1C<sup>20,24,36</sup>; however, real-world observational data *do* show a greater reduction in A1C.
- From a safety standpoint, contact dermatitis is the primary drawback of CGMs.
- CGMs can provide patients and clinicians with a comprehensive picture of daily glucose trends, which can help patients make lifestyle changes and serve as a positive reinforcement for the effects of diet and exercise. Analysis of glucose trends can also help clinicians confidently make decisions about when to intensify or taper a medication regimen, based on data that is reported more often than 90-day A1C changes.

Health insurance coverage will continue to dictate access to CGM technology for many patients. When a CGM is reimbursable by the patient's insurance, consider offering it as an option—even for patients who do not require an intensive insulin regimen. **JFP**

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➤ **Once Medicare covers a continuous glucose monitor, the patient is no longer able to obtain fingerstick glucose supplies through Medicare.**



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