Case Studies in Continuous Glucose Monitoring

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CONTINUING MEDICAL EDUCATION

OBJECTIVES

At the end of the activity, participants will be able to:

- Comfortably prescribe continuous glucose monitoring (CGM) for all appropriate patients.
- Recognize patterns shown in the ambulatory glucose profile (AGP) that may create challenges for the treatment plan.
- Modify the treatment plan based on CGM data to improve patient outcomes and increase time in range (TIR).
- Recognize and address treatment disparities in an effort to make CGM more accessible to patients.

KEY TAKEAWAYS

- Use of CGM is an important consideration for treating all patients with diabetes, including those with type 2 diabetes who are not taking insulin.
- Clinicians should select patients who are candidates for CGM based on their clinical characteristics, ability to access the equipment and supplies, and willingness to use CGM.
- Accurately interpreting the AGP, including metrics such as TIR, is necessary for making treatment decisions based on CGM data.
- Clinicians should seek to be aware of Medicare requirements for CGM coverage and reimbursement, including billing codes for CGM.

TARGET AUDIENCE

Family physicians and clinicians who wish to gain increased knowledge of and greater competency regarding primary care management of diabetes.

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INTRODUCTION

The usefulness and benefits of continuous glucose monitoring (CGM) are increasingly recognized in evaluation and treating patients with diabetes. The American Diabetes Association (ADA) recommends that patients diagnosed with diabetes that requires insulin management should be offered CGM at the outset of treatment.[1] Data from a recent systematic review and meta-analysis also indicate that patients with type 2 diabetes (T2D) without insulin treatment may benefit from CGM use.[2] CGM allows clinicians and patients to move

beyond traditional self-monitoring of blood glucose, with access to more data obtained outside of the clinic, and more insights into patients' blood glucose patterns. Once the data are obtained, however, the clinician must act on the information for it to be of benefit to the patient.

Recognized benefits of CGM to patients include opportunities for increased engagement with their own disease; ability to predict future glucose trends using the rate of change arrows on CGM devices, which show the direction and rate of glucose changes; recognition of the glycemic effects of food, time of day, activity level, and illness; and peace of mind for loved ones or caregivers.[3] For clinicians, CGM benefits include increased patient engagement, better hypoglycemic awareness that can improve prevention, greater insight into therapeutic impacts on glucose management, and use of automated documentation to aid in data visualization.[4] Additionally, in patients for whom glycated hemoglobin (HbA1c) measurements are less reliable, such as those with hemoglobinopathies, CGM is a valuable option for assessing glycemic control.[5]

Candidates for CGM. Identifying the right patient for CGM is critical. Patients who are candidates for CGM might include those ≥2 years of age who need or want more engagement with their diabetes, those who are at risk for hypoglycemia (eg, patients of younger or older age, patients taking insulin), those who need modification of current treatment or are experiencing clinical inertia, and those with poorly managed diabetes who would benefit from greater understanding of diet, activity, and medication on glycemic management.[6]

Assessing whether a patient is a good candidate for CGM might involve asking 3 questions to determine accessibility and utility:

- Will my patient have insurance coverage for a CGM device or be able to afford it?
- Is my patient willing to wear a CGM device?
- Is my office ready to take full advantage of the wealth of information CGM can offer?

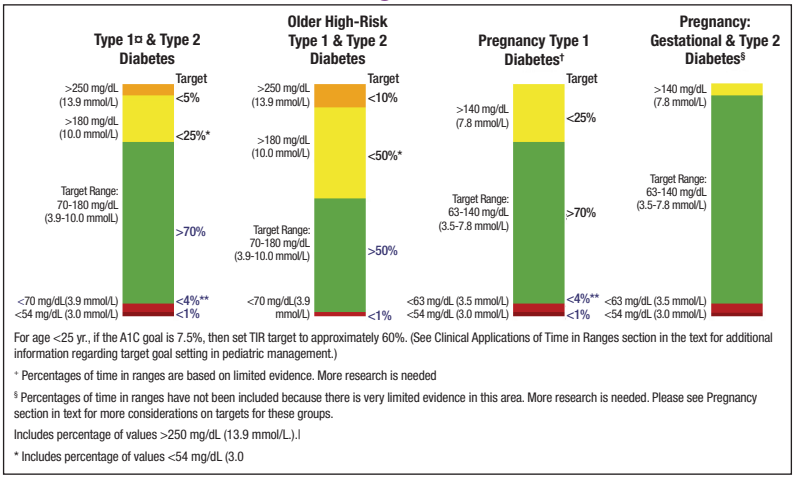
Currently approved CGM devices. Two general categories of CGM devices are currently approved by the US Food and Drug Administration (FDA): personal and professional (**TABLE 1**). Personal devices are patient owned and can be used daily. They can be stand-alone devices or link to other compatible devices (such as insulin pumps). Professional CGM devices are owned by the clinician and loaned to the patient, and some are approved for multiple uses when cleaned and used according to labeling. Professional devices tend to be used for a shorter duration (3–14 days) than personal CGM devices, which can be used indefinitely as long as the patient obtains supplies. Professional CGM devices can be set to have the data "blinded" or "unblinded" to the patient, depending on the scenario.[1]

Interpreting the AGP. The ambulatory glucose profile (AGP) is a report detailing the patient's blood glucose trends. Further explanation of this report will be illustrated later in the article in the context of the case studies. Glucose profile metrics included in the AGP include ideal time in range (TIR) depending on patient characteristics (**FIGURE 1**).[8] Generally, there are 9 steps that can be applied to successful AGP interpretation[9]:

1. Download and print AGP report
2. Check for adequate data (70% active sensor time over 14 days)
3. Look for patterns of low glucose levels/hypoglycemic risk
4. Look for patterns of high glucose levels
5. Look for areas of wide glucose variability/range of glucose values (glycemic variability target ≤36%)
6. Determine appropriate TIR
7. Ask the patient what they see when they look at the AGP
8. Discuss potential solutions and agree on an action plan based on the AGP
9. Mark the AGP report and copy at the end of the visit for the patient

Selected CGM studies. A retrospective, observational study presented at the 80th ADA scientific sessions in 2020 evaluated the change in HbA1c at 6 and 12 months in patients with T2D after starting a CGM.[10] The 2 patient groups were those taking long-acting insulin and those on non-insulin treatment. Adults who had a baseline HbA1c ≥6.5% within 6 months prior to the

Figure 1. CGM-based blood glucose targets for different populations with diabetes, according to the International Consensus on Time in Range.[8]



For age <25 yr., if the A1C goal is 7.5%, then set TIR target to approximately 60%. (See Clinical Applications of Time in Ranges section in the text for additional information regarding target goal setting in pediatric management.)

* Percentages of time in ranges are based on limited evidence. More research is needed

§ Percentages of time in ranges have not been included because there is very limited evidence in this area. More research is needed. Please see Pregnancy section in text for more considerations on targets for these groups.

Includes percentage of values >250 mg/dL (13.9 mmol/L).|

* Includes percentage of values <54 mg/dL (3.0

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Table 1. FDA-approved personal and professional CGM devices.[7]

Personal CGM Devices				
	Abbott FreeStyle Libre 14-day/2 and 2 Plus/3	**Dexcom G6/G7/ Stelo**	**Medtronic Guardian Sensor 3 and 4 (pump integrated) and Guardian Connect (stand-alone)**	**Senseonics Eversense**
Approved labeling	Replaces fingersticks for treatment decisions; no fingerstick calibration required	Replaces fingersticks for treatment decisions; no fingerstick calibration required	Requires ≥2 fingerstick calibrations/d	Replaces fingersticks for treatment decisions; requires 1 fingerstick calibration/d after 21 d
Age	≥18 y/≥2 y	≥2 y	≥14 y/≥7 y	≥18 y
Medicare coverage	Yes/Yes	Yes	Sensor 3/4: Yes Connect: No	Yes
Wear length	14 d/2 and 3 – up to 15 d new 2 plus	10 d	7 d	90–180 d
Warmup	1 h	2 h/27 min	2 h	24 h after implantation
Alarms	No/Yes	Yes	Yes	Yes
Data display/ integration	Reader; Android, iPhone apps; Libre 2 plus integrated with Tandem (Pending integration with Omnipod 5 in 2024)	Reader; Android, iPhone apps; smartwatches; Tandem pump, iLet (Pending Omnipod 5 in 2024)	630G, 670G, 770G, 780G pump (Sensor 4 only); Guardian Connect; Android, iPhone apps	Android, iPhone apps
Form	Disposable transmitter integrated with sensor patch	G6: Transmitter (3-month use) separate from sensor/G7 integrated transmitter	Transmitter (rechargeable) separate from sensor	Transmitter (rechargeable) separate from sensor
Accuracy*	3 = 7.9% (others less accurate)	9%/8.2%	9.6%/9%–11%	8.5%–9.5%
Professional CGM Devices				
	Abbott FreeStyle LibrePRO	**Dexcom G6 Pro**	**Medtronic IPro 2**	—
Blinded or unblinded	Blinded	Either	Blinded	—
Wear time	14 d	10 d	6 d	—
Calibration	0	0	3–4 times daily	—
Care between use	Disposable sensor/ transmitter	Disposable sensor/ transmitter	Sensor must be cleaned and disinfected	—
Insertion	Single-step process with auto-inserter	Two-step process that includes inserting sensor and attaching transmitter	Multistep process that includes inserting and taping both the sensor and transmitter	—
Site	Upper arm	Abdomen	Abdomen	—
Downloading/data reports	LibreView (download in office)	Blinded: Clarity (download in office) Unblinded: apps only	Carelink (download in office)	—

*Accuracy measured by mean absolute relative difference relative to venous glucose; lower values mean the CGM is more accurate. Accuracy figures provided by manufacturers.

Abbreviations: CGM: Continuous Glucose Monitoring; FDA, US Food and Drug Administration.

index date were included. Significant reductions in HbA1c were observed for both groups at 6 and 12 months.[10] After 6 and 12 months of CGM use, HbA1c was reduced by 0.8% (n = 774) and 0.6% (n = 207), respectively. Patients in the non-insulin group experienced a greater reduction in HbA1c at 6 months (0.9%, n = 497) and 12 months (0.7%, n = 120) compared to the overall population ($P < 0.0001$).

In a randomized trial, Martens et al evaluated the effectiveness of CGM in adults with T2D treated with basal insulin (without prandial insulin) in primary care practice.[11] The trial took place from July 2018 to July 2020, and patients were randomly assigned 2:1 to CGM (n = 116) or traditional blood glu-

cose meter (BGM) monitoring (n = 59). Among participants who completed the trial (n = 165), mean baseline HbA1c was 9.1%. The mean HbA1c at 8 months decreased to 8.0% in the CGM group and 8.4% in the BGM group (adjusted difference, –0.4%; 95% CI, –0.8% to –0.1%; P = 0.02). Compared with BGM, adults with T2D using a CGM device had significantly lower HbA1c levels at 8 months.[11]

Coverage and billing codes. To effectively implement CGM within practice settings, clinicians must be aware of CGM coverage (primarily Medicare criteria) and billing codes for CGM. Relevant CGM billing codes are reviewed in **TABLE 2**.[12,13]

Medicare criteria when ordering CGM include the following[14]:

- Patient has diagnosis of diabetes
- Patient is insulin treated with at least 1 injection daily, has had an acute related diabetes event, or has a chronic condition that puts them at risk for hypoglycemia (no documentation of fingerstick required)
- Insulin regimen requires frequent adjustments on basis of CGM data
- Clinic visit within 6 months prior to ordering CGM to evaluate glucose control and determine that the above criteria are met
- Following initial prescription of CGM, in-person visit with clinician every 3–6 months to assess adherence to CGM regimen and diabetes treatment plan (document in chart as notes may be requested)

Note that for some patients, CGM may be covered under the Part B (durable medical equipment) Medicare benefit. The 2 case studies below illustrate examples of how CGM might be used in clinical practice.

CASE STUDY 1

67-year-old white man who has Medicare and lives in a rural area

Past medical history (PMHX): T2D (diagnosed at age 51), coronary artery disease (CAD), hypertension, obesity, hyperlipidemia, and kidney disease with macroalbuminuria

Labs: Stage 3a A3 kidney disease with proteinuria, HbA1c was 9.4% 2 months ago

Estimated glomerular filtration rate (eGFR), 57 mL/min/1.73 m^2; urine albumin-creatinine ratio (UACR), 460; weight, 312 pounds; height, 73 inches; body mass index (BMI), 41.5 kg/m^2; blood pressure, 141/89 mm Hg

Medications:

- Metformin 1000 mg twice daily
- Glipizide 4 mg twice daily
- Dulaglutide 3 mg once weekly
- Empagliflozin 10 mg daily started approximately 3 months ago (no HbA1c testing since start of empagliflozin)
- Lisinopril 10 mg daily, fenofibrate 48 mg daily, aspirin 81 mg daily, simvastatin 40 mg daily
- Currently takes 2 injections of basal insulin per day (not FDA approved); insulin glargine 50 units in the morning and 65 units in the evening

Chief complaint: The patient would like "better results" with his T2D and comorbidities. He'd like better glycemic control and is interested in medication therapies that are specifically designed for his unique health care needs and comorbidities since he felt this wasn't the case in the past. He notes that he has not typically had previous problems with hypoglycemia.

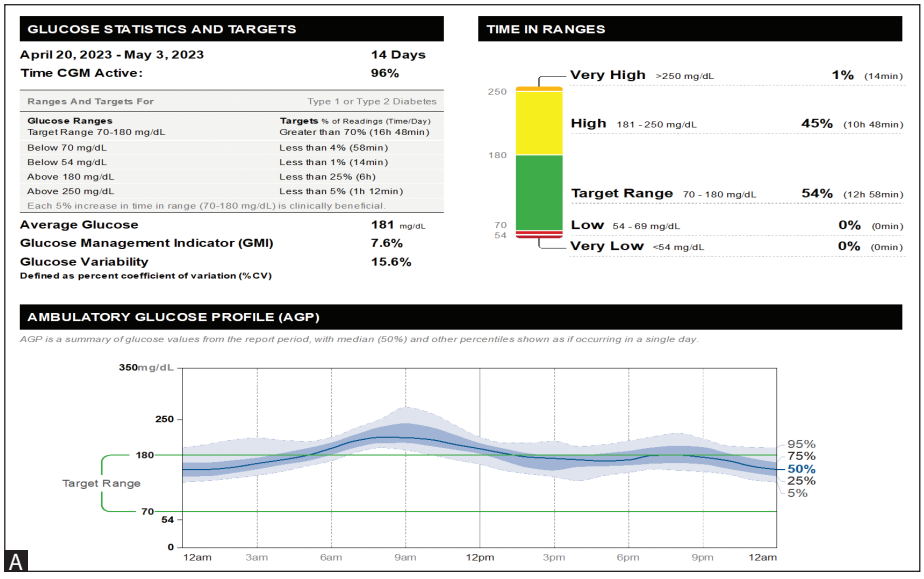
In this case scenario, the patient is a candidate for CGM. A professional CGM device was applied in office, with instructions for the patient to begin keeping a record of how his life-

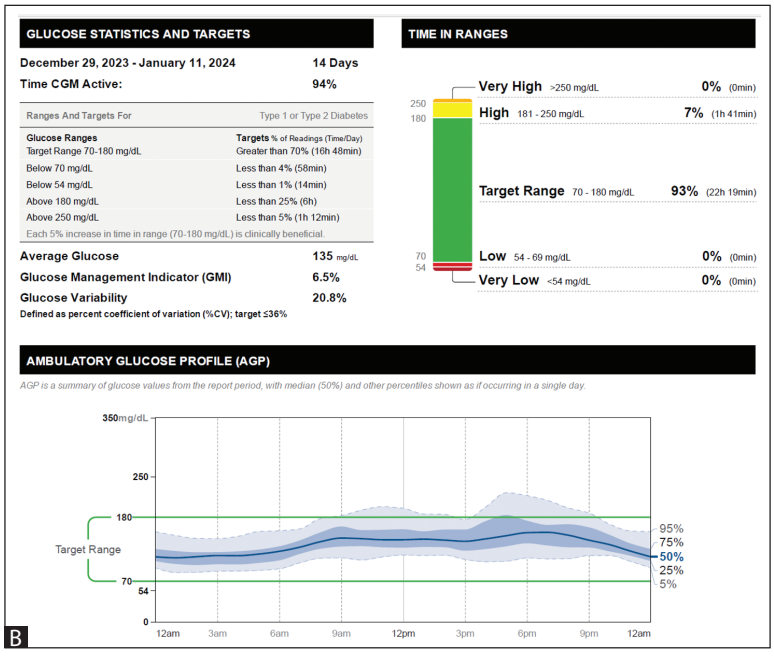
Table 2. Codes for billing CGM.[12,13]

ICD Codes	Description
95249	Personal CGM—Startup/Training: Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hookup, calibration of monitor, patient training, printout, or copy of report (Do not report more than once while patient owns device)
95250	Professional CGM—Ambulatory continuous glucose monitoring of interstitial fluid via a subcutaneous sensor for a minimum of 72 hours; clinician-provided equipment, sensor placement, hookup, calibration of monitor, patient training, removal of sensor, and printout of recording (Do not report more than once per month)
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report (Do not report more than once per month) **May be billed separately or with an E & M visit in person or remote**
99212–99215	Evaluation and Management (E/M) codes; established patient visit or G0463 (Medical Outpatient Clinic Visits)
0446T–0448T	**Eversense-Only Codes** **0446T:** creation of subcutaneous pocket with insertion of implantable sensor, including system activation and patient education **0447T:** removal of implantable sensor from subcutaneous pocket via incision **0448T:** removal of sensor with creation of new pocket for new sensor at a different location, including system activation

Abbreviations: CGM: continuous glucose monitoring; E/M: Evaluation and Management

Figure 2. Case study 1 AGP report at 3-week follow-up (A) and 6-month follow-up (B).





style choices affect his glucose. Glipizide was discontinued due to a history of CAD, empagliflozin was increased to 25 mg daily, dulaglutide was replaced with tirzepatide (titrated to 15 mg once weekly over 6 months), and insulin glargine was changed to 90 units in the evening, titrated daily to fasting morning glucose of <100 mg/dL.

The AGP was reviewed 3 weeks after application, and the patient reported seeing the effects that food choices and exercise have on his glucose numbers (**FIGURE 2**). At the 6-month follow-up, his weight had decreased to 284 pounds, BMI to 37.47 m/kg^2, HbA1c to 6.7%, UACR to 123, and his eGFR remained 57 mL/min/1.73 m^2. The patient had reached a dose of tirzepatide 15 mg once weekly and insulin glargine 108 units once daily. Note that on the 6-month follow-up AGP, his TIR is 93% compared to 54% at the 3-week follow-up (**FIGURE 2**).

CASE STUDY 2

42-year-old Asian woman with T2D

PMHX: T2D, microalbuminuria without hypertension, hyperlipidemia

At her last appointment with her primary care physician, initiation of insulin was discussed.

Labs: HbA1c, 8.2%; eGFR, 62 mL/min/1.73 m^2; UACR, 34; Body mass index, 27.98 m/kg^2; height, 62 inches; weight, 153 pounds; blood pressure, 121/89 mm Hg

Medications:

- Glipizide 4 mg twice daily
- Metformin 1000 mg twice daily
- Lisinopril 10 mg daily
- Stopped statin due to muscle aches
- Previous medications tried and discontinued include a sodium-glucose cotransporter-2 (SGLT-2) inhibitor (side effect: yeast infections) and dulaglutide (side effect: severe gastrointestinal heartburn)

Chief complaint: The patient is frustrated with her overall glucose control but does not want to take insulin. She doesn't have a lot of time and works all day with her hands (as a hairdresser), which makes it difficult to use a traditional self-monitoring of blood glucose system.

The patient is willing to try a CGM device to help manage her T2D in addition to other medication changes. A CGM device was applied in the office, glipizide was discontinued, tirzepatide was titrated to 7.5 mg once weekly over 3 months, dapagliflozin was started with perineal care instructions to avoid vulvar irritation, and the patient was engaged to be attentive to the effects of food, stress, and exercise on glycemia.

A review of 3-week follow-up AGP data (**FIGURE 3**) revealed to the patient that she had high blood sugar most of the time (time above range 89%). The patient could see that there were opportunities to improve her meal choices. At a 5-month follow-up, the patient's blood glucose demonstrated a significant clinical response to lifestyle intervention and medication change (**FIGURE 3**).

FUTURE DIRECTIONS

In addition to expanded CGM coverage expected in the future, clinicians can look forward to newer concepts in CGM use such as insulin pump integration and continuous glucose-ketone monitoring. There are currently several CGM and insulin pump devices that automatically adjust insulin dosing based on CGM measurements via integration to mitigate the risks of critical glucose episodes.[17,18] Of note, several new over-the-counter CGM systems were recently approved in the US: Lingo (Abbott), Libre Rio (Abbott), and Stelo (Dexcom).

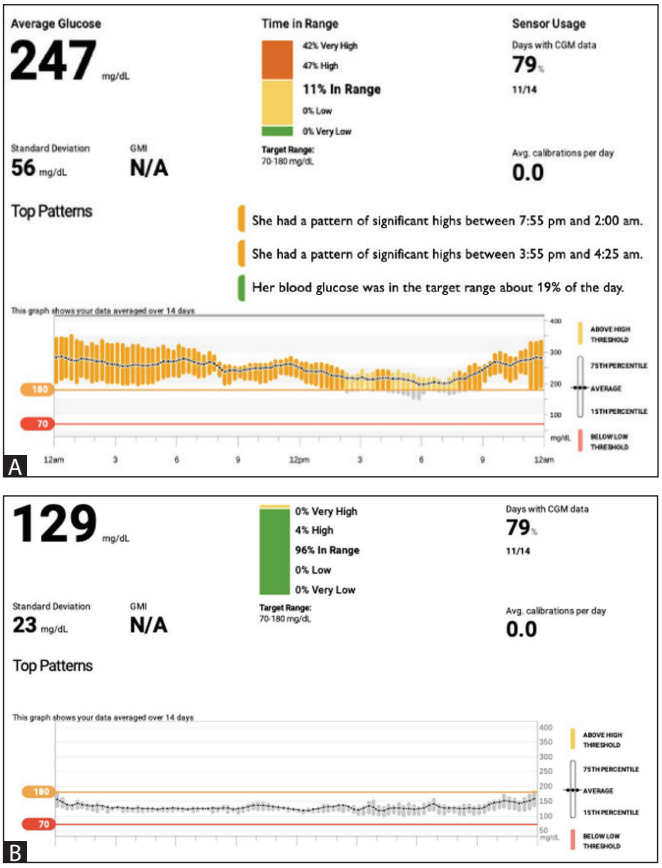
The need for continuous ketone monitoring has been recognized as potentially useful for certain conditions such as recurrent diabetic ketoacidosis, pregnancy, and anorexia, as well as during exercise, on sick days, and with medications that can increase the risk of diabetic ketoacidosis.[19] Integration of continuous ketone monitoring and CGM in the same sensor platform is an important consideration for potential implementation of these concepts.[19] Integrated CGM-ketone sensors are actively being studied in clinical trials, with 1 device receiving FDA breakthrough designation status. This technology may reach clinical practice in the next few years.

SUMMARY

Use of CGM is an important consideration for all patients with diabetes, including those with T2D who are not taking insulin. Before prescribing CGM, clinicians should consider both the patient's ability to successfully access the CGM device and supplies and their willingness to use CGM. Future advances in CGM might include expanded coverage, smaller and more accurate devices with better connectivity, and devices tailored to patients with T2D.

More information on CGM is available; a resource toolkit page can be found at https://www.pcmg-us.org/ toolkit/cgm. This toolkit offers an array of links to help clinicians establish an effective CGM practice workflow. The toolkit also includes a webinar (offering additional CME credit), links to every source cited in this article, additional case studies, and explanations of AGPs, as well as specific information about device insertion, data access, and details on each device currently approved by the FDA. ●

Figure 3. Case study 2 AGP report at 3-week follow-up (A) and at 5-month follow-up (B).



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