Common Questions on Continuous Glucose Monitoring in Primary Care

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CONTINUING MEDICAL EDUCATION

LEARNING OBJECTIVES

- Identify patients who are good candidates for a continuous glucose monitor (CGM) vs fingerstick self-monitoring of blood glucose (SMBG)
- Discuss the information provided by CGM systems
- Generate and interpret patient CGM data using the ambulatory glucose profile (AGP) to assess time targets established by the International Consensus on Time in Range
- Modify the treatment plan based on CGM data to improve patient outcomes

KEY TAKEAWAYS

- CGM overcomes some of the limitations of glycated hemoglobin and fingerstick SMBG.
- The standardized AGP and time in range (TIR) have been established to serve as an actionable format for presenting and interpreting CGM data.
- For most healthy adults with type 1 (T1D) or type 2 diabetes (T2D), the desired target for TIR (70-180 mg/dL) is ≥70%.
- The AGP provides glycemic patterns that facilitate the identification of glucose variability, hyperglycemic episodes, and individuals at high hypoglycemic risk.
- The AGP is particularly useful for individuals treated with insulin, but the benefits of CGM and AGP are not limited to individuals using insulin.
- The AGP provides an excellent opportunity for shared decision-making and increased patient engagement.

TARGET AUDIENCE

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

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RESOURCE TOOLKIT

WHAT IS CONTINUOUS GLUCOSE MONITORING AND WHICH PATIENTS WILL BENEFIT FROM ITS USE?

Continuous glucose monitoring (CGM) is a method of measuring glucose by means of a small medical device that measures interstitial glucose continuously over time, unlike fingerstick self-monitoring, which only provides the blood glucose at the time of the testing by measuring capillary plasma glucose concentrations.[1] The venous or capillary glycated hemoglobin level (A1c) shows an aggregate measure of blood glucose levels over a period of approximately 3 months.[2] Real-time CGM shows how various activities (like eating or exercise) impact glucose over time, and allows the patient and the clinician to see treatment issues not otherwise revealed by either fingerstick testing or A1c, such as glycemic variability.

The limitations of the A1c are readily apparent. Because it is an aggregate measure, a patient with a constant glucose value of 154 mg/dL (no glycemic variability) is likely to have the same A1c result as a patient with glucose values of 64 mg/dL half of the time, and 244 mg/dL the other half of the time: 7.0%. In this hypothetical situation, one of these patients is well controlled and the other is not, although their A1c results may be precisely the same (**FIGURE 1**).

CGM offers a host of real-world benefits, including improved glycemic control. The control of glucose at levels close to physiologic levels in humans is well established as conferring numerous benefits, such as weight control and reduced risk for cardiovascular disease, as demonstrated in clinical studies.[3-10] CGM is recommended by the American Diabetes Association for individuals with diabetes who are receiving multiple daily injections, continuous subcutaneous insulin infusions, and other forms of insulin therapy.[11] Other candidates for CGM include individuals who are not at goal and those with frequent hypoglycemia or hypoglycemia unawareness, taking other medications that cause low blood glucose, with kidney disease, and with varying and/or intensive activity, as well as those who have a desire to improve glycemic control and are willing and able to use CGM.[12-14] Key benefits of CGM use include early warnings of high, low, and/or rapidly changing glucose levels, and CGM clearly shows the results of patient actions and subsequent consequences. This author does not feel there are any poor candidates for CGM as all people with diabetes could benefit on some level from the data and insight it provides. CGM use must take into consideration the cost/benefit ratio, which may vary between individuals as to the frequency of use, professional or personal CGM device used, and objectives for use (eg, modification of treatment intervention, determination of the impact that diet and activities of daily living are having on glycemia, identification of glucose variability, or prevention of hypoglycemic events). Additional background information about CGM may be found at https://pro.aace.com/pdfs/diabetes/AACE-DRC-CGM-Slides.pdf.[15]

WHAT ARE THE AVAILABLE US FOOD AND DRUG ADMINISTRATION (FDA)–APPROVED OPTIONS FOR CGM?

There are currently 5 CGM devices approved for use in the United States (**TABLE 1**). Clinicians should be aware that, for their patients on an insulin pump, some of these devices may offer pump integration.

FIGURE 1. **Examples of a 7.0% A1c**

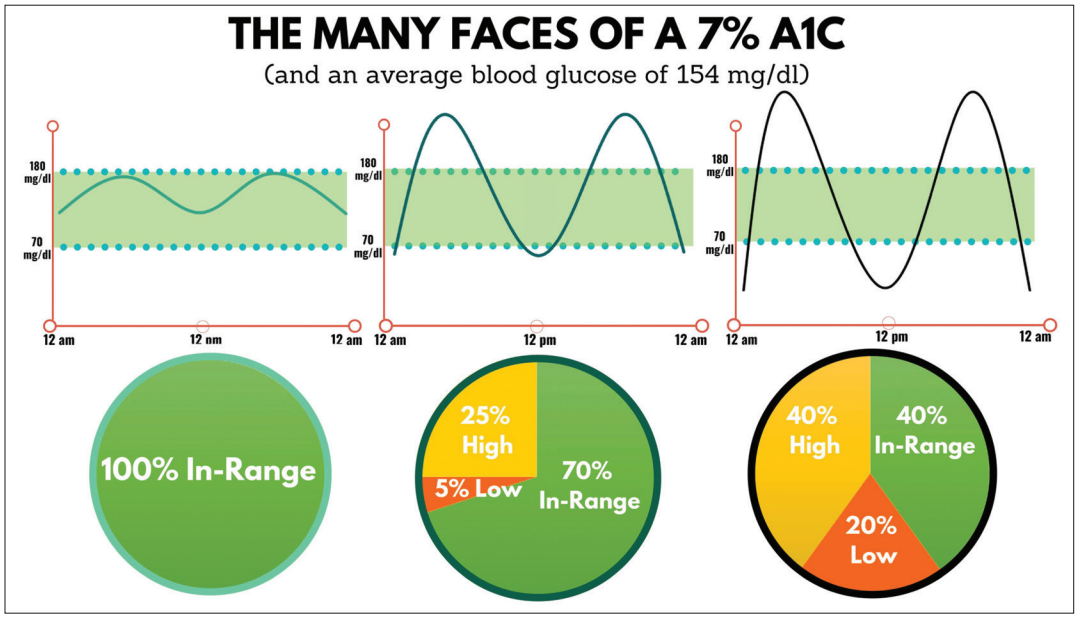

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TABLE 1. **FDA-approved CGM devices**

	Abbott FreeStyle Libre 14-Day	Abbott FreeStyle Libre 2 (FreeStyle Libre 3 recently received FDA approval)	Dexcom G6 (G7 awaiting FDA approval)	Medtronic Guardian Sensor 3 (pump integrated) and Guardian Connect (stand-alone)	Senseonics Eversense (subcutaneous insertion by clinician)
Approved labeling	Replaces fingersticks for treatment decisions; no fingerstick calibration required	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 ≥2 fingerstick calibrations/d
Age	≥18 y	≥4 y	≥2 y	≥14 y	≥18 y
Medicare coverage	Yes	Yes	Yes	Sensor 3: Yes Connect: No	Yes
Wear length	14 d	14 d	10 d	7 d	180 d
Warmup	1 h	1 h	2 h	2 h	24 h after insertion
Alarms for lows, highs	No	Yes	Yes	Yes	Yes
Data display	Reader; Andriod, iPhone app	Reader; Android, iPhone app	Reader; Android, iPhone app; smartwatches; Tandem pump	Android, iPhone app; 630G, 670G or 770G pump; Guardian Connect	Android, iPhone app
Form	Disposable transmitter integrated with sensor patch	Disposable transmitter integrated with sensor patch	Transmitter (3-month use) separate from sensor	Transmitter (rechargeable) separate from sensor	Transmitter (rechargeable) separate from sensor

HOW DO I ACCESS THE CGM DATA?

The ambulatory glucose profile (AGP) is produced by a software application that aggregates CGM data to characterize glycemic exposure, variability, and stability, overlaying all data from the survey period as if it were a single day. While every AGP has a similar format, every brand of CGM offers a different mechanism for accessing the data (**TABLE 2**).

ONCE I HAVE THE AGP, HOW DO I USE THE DATA TO INTERVENE CLINICALLY?

An adequate time period is needed for pattern recognition. The time period covered by the AGP is determined by the user, and the length allowed varies by the CGM device. A 14-day report is considered adequate for pattern recognition and is generally viewed as being statistically similar to a 90-day report.[15] For individuals with greater glycemic variability, exhibited by wide fluctuations or variability in the glucose level (eg, coefficient of variation ≥36%), longer CGM collection periods may be required.

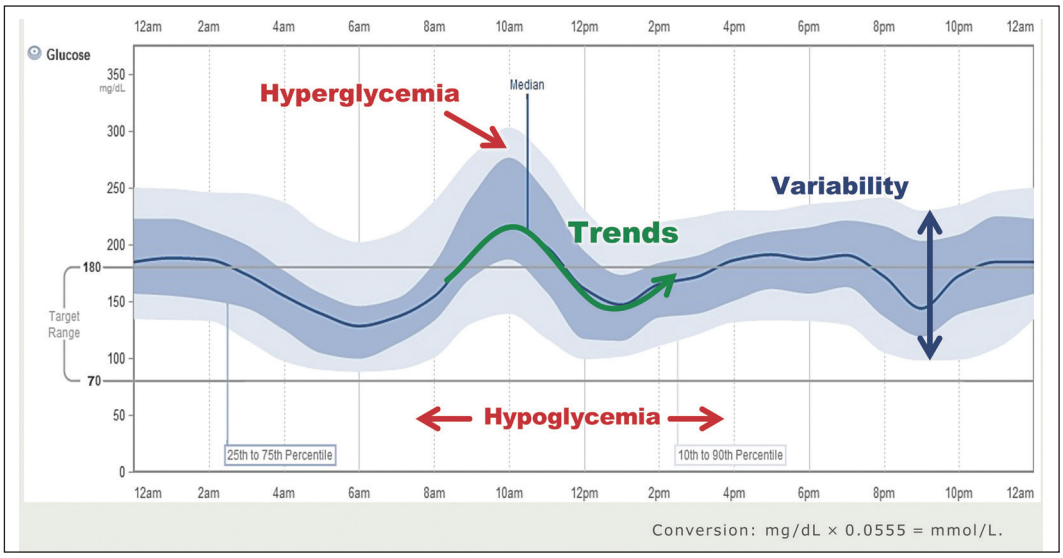
For ease of interpretation, the AGP is presented visually as a modal day plot according to time as if the data points collected over 7, 10, or 14 days occurred over 24 hours

TABLE 2. **Accessing CGM data**

Device	URL	Details
Abbott FreeStyle Libre	https://www.freestyleprovider.abbott/	LibreView or FreeStyle Libre Pro
Dexcom G6	https://provider.dexcom.com/products	Dexcom Clarity for Professional Data Analysis
Medtronic Guardian Sensor 3	https://www.medtronic.com/us-en/healthcare-professionals/products/diabetes/data-management-software/carelink.html	Carelink
Senseonics Eversense	https://www.ascensiadiabetes.com/eversense/hcp/	Eversense Data Management System (DMS) Pro

(**FIGURE 2**). The AGP includes 3 key CGM measurements: time within target range (TIR), time above target range (TAR), and time below target range (**FIGURE 3**).[16] Other helpful metrics include the average glucose, which is used to calculate the glucose management indicator (GMI), an approximate A1c if levels remained here for 2 to 3 months.

FIGURE 2. **Ambulatory glucose profile**



Increasing TIR is the primary goal, with the added benefit of reducing glycemic variability, and, particularly, hypoglycemia. For many individuals with T1D or T2D, the TIR should be ≥70%, as this correlates with better glycemic control, ie, A1c <7.0%. TIR >50% may be appropriate for individuals who are older or who have comorbidities (eg, cognitive deficit, renal disease, joint disease, osteoporosis, fracture, and/or cardiovascular disease) that place them at higher risk of complications.[14] It is recommended that pregnant woman should aim for a TIR of >70% (16 h, 48 m) and a TAR of <25% (6 h), from as early as possible during the pregnancy for optimal neonatal outcomes.[17] Glycemic targets differ in pregnancy compared to the general population.

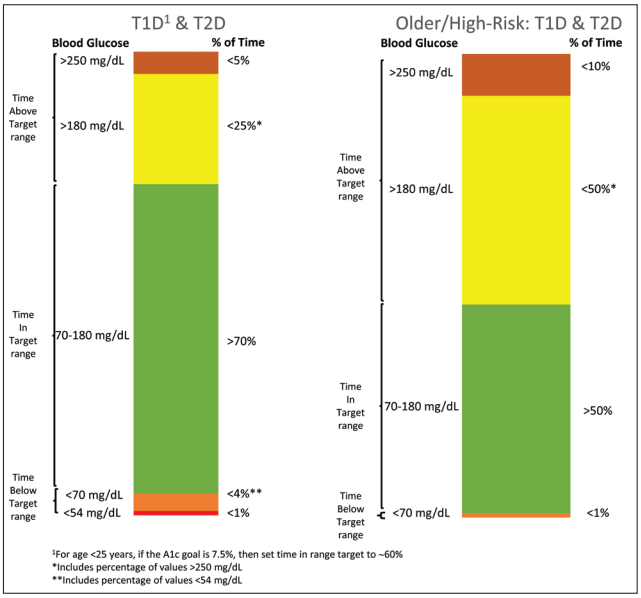
Interpreting the AGP provides an opportunity for shared decision-making and collaborating with the patient to identify situations where the glucose level is and is not well controlled. Discussion may then focus on reinforcing behaviors contributing to good glycemic control, as well as overcoming challenges that may contribute to poor glycemic control.

CASE STUDY

- 77-year-old male with T2D (11 years)
- History of hypertension, hyperlipidemia, high blood pressure (now controlled), and coronary artery disease
- A1c = 7.8%
- Current Medications:
  - Metformin extended-release tablets (500 mg), 2 in AM
  - Losartan 50 mg daily
  - Atorvastatin 40 mg daily
  - Amlodipine 10 mg daily
  - Clopidogrel 75 mg daily
  - Lantus 12 units in the PM and 10 units in the AM

Sodium-glucose cotransporter 2 inhibitors and glucagon-like peptide-1 receptor agonists have been suggested but were declined due to cost. Patient tests his glucose once per day

FIGURE 3. **CGM targets for different populations with diabetes[16]**



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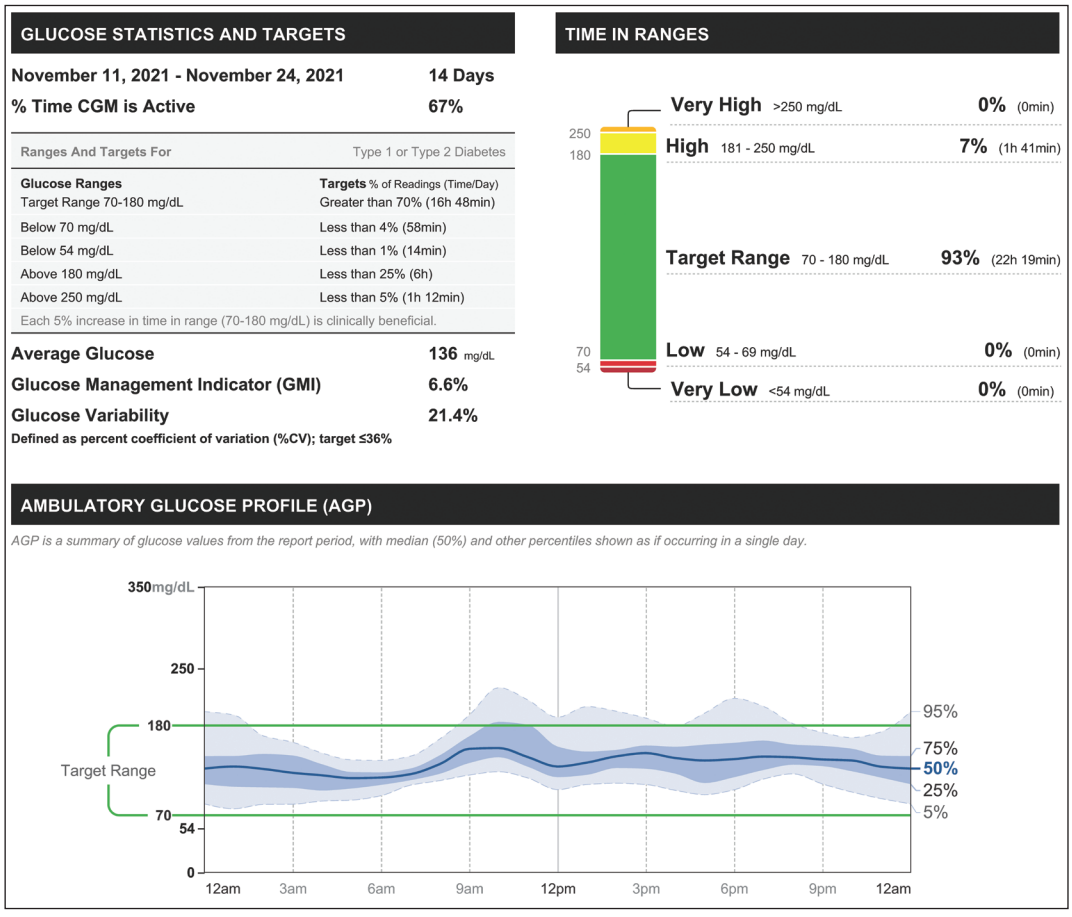
in the morning and he notes high blood glucose readings and great variability.

The patient agreed to wear a CGM for 2 weeks and was provided instruction on keeping a meal and activity log. He was also asked not to split the dose of his long-acting insulin, but rather to take it one time per day as approved, starting with 25 units in the evening and adding 1 unit every day until his fasting morning glucose falls below 140 mg/dL.

In the follow-up appointment, the patient was asked what he had learned from the experience of wearing a CGM for 2 weeks. He indicated that logging his diet, activity, sleep, and stress level combined with the real-time glucose data the CGM provided offered enormous insight into the impact his activities had on his overall glycemic control. He changed his breakfast from oatmeal to egg whites and sauteed vegetables. He up-titrated his insulin to achieve his target fasting blood sugar of <140 mg/dL, and within a week's time was able to be consistently at target (with 28 units). He realized that he was not experiencing any hypoglycemic episodes and noted that exercising in the afternoon helped maintain his control through dinner. He chuckled over the impact that some Thanksgiving cheesecake had on his numbers. He asked to continue using a CGM. If he maintains the excellent control he achieved with his CGM, the GMI shown on his AGP suggests that his next A1c would likely be about 6.6% (**FIGURE 4**).

FIGURE 4: **Case study**



WHAT ARE THE KEY ELEMENTS TO OBTAINING MEDICARE, MEDICAID, AND PRIVATE INSURANCE COVERAGE?

Medicare coverage criteria for CGM were updated in 2021 to eliminate extensive blood glucose log data, making obtaining coverage less daunting.[18] The prescribing clinician must provide supporting clinical indications for CGM. Coverage can be expected if the patient is insulin-treated with ≥3 daily injections of insulin or is using a pump, and the patient's insulin treatment regimen requires frequent adjustments on the basis of glucose readings. In addition, the patient must have been seen by the clinician within 6 months of the order to evaluate diabetes mellitus (DM) control and determine that the above criteria are met. Following the initial prescription, the patient must have in-person visits with the clinician every 6 months to assess adherence to the CGM regimen and the DM treatment plan. The CGM must be ordered through durable medical equipment (DME), not the pharmacy.

Medicaid coverage varies from state to state, and states with expanded Medicaid usually offer more coverage options. Information for each state's Medicaid program can be found at the diatribechange.org website: https://bit.ly/3okAdUg. What is covered, who is covered, and at what cost also varies among private insurance policies. Patients with T1D and those with T2D who are on an insulin regimen are likely to

TABLE 3. **Codes for billing for CGM**

Code	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, hook-up, calibration of monitor, patient training and printout of recording. (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, hook-up, 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.)
99212-99215	Evaluation and Management (E/M) Codes: Established Patient Visit or G0463 (Medicare Outpatient Clinic Visits).
0446T, 0447T, and 0448T	Eversense codes only: for insertion (including system activation and patient training) and removal of implantable interstitial glucose sensor. (Do not report any in conjunction with others of this set of codes; do not report 0446T in conjunction with 95251.)

have coverage. Detailed patient notes, describing the reasons CGM is needed, are helpful. Shared decision-making should also play a role here, with the patient able to take the lead and determine which CGM options are available by way of their insurance coverage.

In a recent comparison of retail costs, Abbott's FreeStyle Libre had the lowest monthly cost, followed by Medtronic, Dexcom, and Eversense.[19] Patient out-of-pocket costs will vary based on numerous factors, including location, discounts, insurance coverage, changing price structures, and manufacturing coupons and incentives at the time of purchase.

HOW DO I DOCUMENT AND BILL FOR CGM?

Relevant billing codes cover all FDA-approved CGM devices (**TABLE 3**). There are additional Senseonic Eversense-specific codes for the insertion and removal of the unique implantable subcutaneous CGM.

SUMMARY

CGM is an important tool for improving care of patients with T1D and T2D. AGP data create the opportunity for more informed clinical decisions and empower the patient to understand the impact of their actions on their glucose more clearly and address issues of glycemic variability. Gaining coverage for CGM is easier now than it has been in the past and is likely to become easier still in the future. CGM is quickly emerging as a standard of care for many patients with diabetes.[20] ●

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