

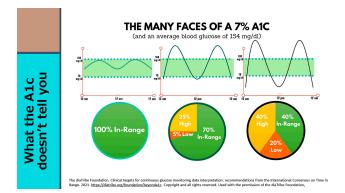
Continuous Glucose Monitoring: Optimizing Diabetes Care: Executive Summary

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Continuous glucose monitoring (CGM) systems are small medical devices used to measure blood glucose continuously over the course of a person's day and, importantly, also throughout the night. More than with A1C or fingerstick blood glucose monitoring (BGM), the data gained from CGM offer tremendous insights into glycemic control and enable both clinicians and people with diabetes to make informed adjustments to treatment plans through shared decision-making. Most CGM devices can be applied and started by the patient independently.

This article is intended to serve as an executive summary for a series of short videos available now on the *Clinical Diabetes* website. The authors discuss the limitations of relying solely on A1C to guide patients' daily decision-making, the advantages of using CGM for both patients and clinicians, the role of the ambulatory glucose profile (AGP) report and time in range (TIR) metric as actionable formats for presenting and interpreting CGM data, strategies to modify patient treatment plans based on CGM data, patient access to and affordability of CGM equipment, and relevant insurance billing codes and other clinician resources. The video series described below is available in its entirety at https://diabetesjournals.org/clinical/pages/ continuous glucose monitoring.

Video Summaries Overview (Video 1)



Video 1. Overview. This image is from a video available online at https://bcove.video/3yKqltv. To receive continuing education credit for viewing this video, go to https://wh1.snapsurveys.com/s.asp?k=164411016242, or, to receive continuing education credit for viewing all four videos, go to https://wh1.snapsurveys.com/s.asp?k=164893979094.

CGM is a method of measuring glucose using a small sensor inserted under the skin. The device measures interstitial glucose continuously over time; in contrast, fingerstick BGM using a traditional glucose meter only provides a blood glucose level at the time of testing by measuring capillary plasma glucose concentrations (1), and venous or capillary A1C testing yields an aggregate measure of blood glucose over a period of \sim 3 months (2). CGM data reveal how various activities (e.g., eating or exercise) affect glucose levels and allow for patients and clinicians to identify and reduce glycemic variability over time.

As previously stated, A1C is an aggregate measure. Thus, a person with a constant glucose level of 154 mg/dL (i.e., no glycemic variability) and a person with glucose values of 64 mg/dL half of the time and 244 mg/dL the other half of the time (i.e., significant glycemic variability) are both likely to have an A1C value of 7.0% (3). In this hypothetical situation, both individuals would have an

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average glucose of 154 mg/dL, resulting in the same A1C, even though one person has well-controlled glycemia and the other does not.

Controlling glycemia to levels as close as possible to the nondiabetic range reduces the risk of microvascular, macrovascular, and neurologic complications (4–12). The American Diabetes Association (ADA) recommends the use of CGM for individuals with diabetes using multiple daily injections, continuous subcutaneous insulin infusion, and other forms of insulin therapy (13). CGM is also recommended for individuals whose glucose levels are not at goal, who have frequent hypoglycemia and/or hypoglycemia unawareness, who are taking other medications that cause low blood glucose, who have kidney disease, or who have varying and/or intensive physical activity patterns. Importantly, individuals must be willing and able to use and have access to a CGM system (14–17).

This video explains how to use the CGM-derived TIR metric (i.e., percentage of time glucose is within the range of 70–180 mg/dL) and highlights the benefits of accessing ongoing glycemic data to detect and treat high, low, and/or rapidly changing glucose levels and to guide daily diabetes management decisions. In addition, CGM studies demonstrating reductions in hospitalizations, work absences, and family worry, as well as improvements in glycemic control and patient satisfaction are discussed (7,9–11,18,19).

Options for CGM (Video 2)



- Must provide supporting clinical indications:
 - History of hypoglycemia unawareness, severe glycemic excursions, patient demonstrated ability to SMBG, etc.
- Evidence of SMBG ≥ 4 times per day (submit BG log) ELIMINATED 7/21
- Patient is insulin-treated with ≥ 3 daily injections of insulin or using pump
 Insulin treatment regimen requires frequent adjustments on the basis of CGM results
- Within 6 months prior to ordering CGM, patient was seen in clinic to evaluate DM control and determine that above criteria are met
- Every 6 months following the initial prescription of CGM, patient has in-person visit with clinician to assess adherence to CGM regimen and DM treatment plan
- MUST be ordered through durable medical equipment (DME), not pharmacy

Video 2. Options for CGM. This image is from a video available online at https://bcove.video/3P9v2SX. To receive continuing education credit for viewing this video, go to https://wh1. snapsurveys.com/s.asp?k=164411019457, or, to receive continuing education credit for viewing all four videos, go to https://wh1. snapsurveys.com/s.asp?k=164893979094.

This video reviews CGM systems that have been cleared by the U.S. Food and Drug Administration (FDA), as well as a device currently under FDA review, providing details including sensor wear-time, Medicare coverage, form of device, and appropriate users for each system. When choosing from among the available CGM systems for specific patients, clinicians should also consider whether the patient is already using an insulin pump. Some CGM systems can communicate directly with specific insulin pumps, allowing patients to view results, receive alerts and alarms, and adjust insulin delivered right from their pump without requiring a separate reader or digital app to view CGM data.

Criteria for Medicare coverage of CGM were updated in 2021 to eliminate the previously required submission of extensive blood glucose log data; this change made obtaining Medicare coverage for CGM less daunting. However, the prescribing clinician must still provide supporting clinical indications for CGM. Coverage is often available for patients who are treated with insulin and using three or more daily injections or an insulin pump in a regimen that requires frequent dose adjustments based on glucose readings. In addition, patients must have been seen by the clinician within 6 months of the order to evaluate their diabetes control and document that all criteria are met. After their initial prescription, patients must have in-person visits with their prescribing clinician every 6 months to assess adherence to the CGM regimen and the diabetes treatment plan. The CGM system must be ordered through Medicare's durable medical equipment benefit; they are not covered through the Medicare pharmacy benefit.

Medicaid coverage varies from state to state, with states with expanded Medicaid usually offering more coverage options (Video 2). Information about each state's Medicaid program is available online (at https://bit.ly/ 30kAdUg).

Among private health insurance plans, what is covered, who is covered, and at what cost varies. People with type 1 diabetes and those with type 2 diabetes who are on an insulin regimen are likely to have coverage. Detailed notes describing the reasons CGM is needed are helpful in securing private insurance coverage. Shared decision-making, in which patients express their preferences and understand their insurance coverage, is essential in selecting the most appropriate system for each patient. Helpful resources are also available through the ADA for both clinicians and patients (https://www.diabetes.org/tools-support/ devices-technology/choosing-cgm).

This video also reviews CGM options for uninsured patients. The authors note that patients' out-of-pocket

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costs will vary based on numerous factors, including their location of residence, insurance coverage, changing price structures, and available discounts, manufacturers' coupons, and incentives at the time of purchase. At the time this roundtable discussion was videotaped, the Freestyle Libre intermittently scanned CGM system (Abbott Diabetes Care) was reported to have the lowest monthly cost, followed by Medtronic, Dexcom, and Eversense CGM systems (20).



Video 3. The Ambulatory Glucose Profile. This image is from a video available online at https://bcove.video/3AAnvZC. To receive continuing education credit for viewing this video, go to https://wh1.snapsurveys.com/s.asp?k=164411021916, or, to receive continuing education credit for viewing all four videos, go to https://wh1.snapsurveys.com/s.asp?k=164893979094.

The Ambulatory Glucose Profile (Video 3)

The AGP is a standardized report provided by all CGM systems that aggregates CGM data to statistically characterize glycemic exposure, variability, and stability.

The time period covered by the AGP is determined by the user, with allowed lengths of time varying by the specific CGM device or the length of time the patient chooses to wear the sensor. A 14-day report is considered adequate for pattern recognition and is generally viewed as being statistically similar to a 90-day report (21). For individuals with greater glycemic variability exhibited by wide fluctuations in glucose levels (e.g., a coefficient of variation >36%), longer data collection periods may be required. AGP reports that include data for time periods shorter than 14 days are still useful, as even a short period of CGM use may reveal insights into patient challenges with glycemic management.

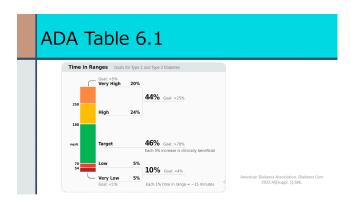
For ease of interpretation, the AGP is presented visually as a modal day plot according to time, as if the data points collected over 7, 10, or 14 days had occurred over a 24-h period. The AGP report also includes three key CGM metrics: TIR, time above range (TAR), and time below range (TBR) (17). Other helpful metrics include the average glucose, which is used to calculate the glucose management indicator, an approximate A1C if levels remained as indicated for 2–3 months.

Increasing TIR is the primary goal of therapy, leading to lower A1C with the added benefits of reduced glycemic variability and, particularly, reduced hypoglycemia.

AGP reports look similar regardless of which CGM system a patient uses, but the method of accessing these reports varies from one system to another. Patients may share an app that allows their clinician to view their AGP report. Many systems also offer clinicians additional options for access and reviewing patients' CGM data and AGP reports.

Interpreting the AGP provides an opportunity for shared decision-making and collaborating with patients to identify situations in which their glucose is or is not well controlled. Discussion may then focus on reinforcing behaviors contributing to improved glycemic control.

The authors conclude this discussion by examining the case of a 61-year-old man with type 2 diabetes for 4 years, who was experiencing symptoms of chronic hyperglycemia and markedly elevated A1C after being lost to follow-up for 3 years. The case study illustrates the dramatic impact CGM can have on disease management, with both the clinician and the patient making changes to the treatment regimen based on the AGP report. The patient was able to achieve a TIR of 99% (general recommendation TIR >70%) within a few months of starting CGM.



Video 4. Billing/Coding and FAQs. This image is from a video available online at https://bcove.video/3RhqvzS. To receive continuing education credit for viewing this video, go to https://wh1. snapsurveys.com/s.asp?k=164411066319, or, to receive continuing education credit for viewing all four videos, go to https://wh1. snapsurveys.com/s.asp?k=164893979094.

Billing/Coding and FAQs (Video 4)

In the final video in the series, the authors delve into the specifics of billing for CGM, including both personal (patient-owned) and professional (clinic-owned) systems. Billable services include sensor placement, system hook-up, calibration, patient training, printout of AGP report, and sensor removal. They also discuss the importance of setting up the clinic environment to facilitate the adoption and ongoing use of CGM in the clinical practice.

The authors also discuss treatment goals for CGM-derived metrics, including the percentage goals for TIR (>70% of time within 70–180 mg/dL), TBR (<4% of time <70 mg/dL and <1% of time <54 mg/dL), and TAR (<25% of time >180 mg/dL, and <5% of time >250 mg/dL) (2).

This video also includes the patient experience with CGM, as offered by an individual with longstanding type 1 diabetes. She shares her diabetes management experiences before and after the initiation of CGM and describes what CGM has meant for her. Finally, the authors discuss some frequently asked questions about CGM and review key takeaway messages from the series.

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DUALITY OF INTEREST

E.M. has served as a consultant, advisory board member, and/or speakers bureau participant for Abbott Laboratories, AstraZeneca, Boehringer Ingelheim, Eli Lilly, Merck, and Novo Nordisk and has received research funding from Abbott Laboratories and Pendulum. J.R.G. has been a consultant and/or speakers bureau participant for Abbott Diabetes Care, Boehringer Ingelheim, Eli Lilly, Intuity Technology, Novo Nordisk, and Xeris. D.F.K. has served on an advisory board and/or speakers bureau for Abbott Laboratories, Cequr, Dexcom, Eli Lilly, Novo Nordisk, Sanofi, and Xeris and has stock options in Pendulum. S.A.B. is editor-in-chief of *Clinical Diabetes*; has served on an advisory board and/or speakers bureau for Abbott Diabetes Care, AstraZeneca, Bayer, Boehringer Ingelheim, Eli Lilly, Sanofi, and Xeris; and has stock options with Paracrine. No other potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

E.M. researched data and provided case study details and AGP results for this work. J.R.G. and D.F.K. researched data. S.A.B. provided editorial review. S.A.B. is the guarantor of this work and, as such, had full access to all the data in the article and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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