CODING GUIDELINES FOR CONTINUOUS GLUCOSE MONITORING

R. Mack Harrell, MD, FACP, FACE, Chair;
Eric A. Orzeck, MD, FACP, FACE, Vice-Chair;
for the American Association of Clinical Endocrinologists
Socioeconomics and Member Advocacy Committee

Abbreviations:
CGM = continuous glucose monitoring; **CGMS** = continuous glucose monitoring system; ***CPT*** = *Current Procedural Terminology*; **FDA** = US Food and Drug Administration

INTRODUCTION AND BACKGROUND

Continuous glucose monitoring (CGM) technology approximates the measurement of plasma glucose levels by continuous measurement of interstitial fluid glucose levels. Some CGM systems (CGMS) provide real-time display of glycemic information, whereas others require data download and retrospective review.

The original CGM device was manufactured by Medtronic MiniMed, Inc. (Northridge, California). Since approval by the US Food and Drug Administration (FDA) of the MiniMed CGMS in 2006, the technology for continuous glucose monitoring has evolved substantially, and CGM now refers to any device that measures and records interstitial glucose concentrations frequently (typically, every 5 minutes) and for a prolonged time frame (3 to 7 days with current technology).

From the Minimally Invasive Endocrine Surgery Center, Imperial Point Medical Center, Fort Lauderdale, Florida.
Address correspondence and reprint requests to Dr. R. Mack Harrell, 3287 Northwest 56th Street, Boca Raton, FL 33496-2523. E-mail: Rmharrell1@aol.com.

APPLICATIONS

CGM devices may be used diagnostically by health care professionals or by carefully educated patients as personal, automatic, real-time glucose monitors with digital display interfaces. CGM is indicated for patients with type 1, type 2, or gestational diabetes who require better regulation of blood glucose levels. Candidates can include patients who need to:

- Reestablish blood glucose control after acute episodes of hypoglycemia, ketoacidosis, hyperosmolar coma, and other complications
- Switch from conventional insulin injections to pump therapy
- Manage sustained elevations of glycosylated hemoglobin or unstable blood glucose levels with large glycemic fluctuations
- Respond to episodes of hypoglycemic unawareness and, especially, frequent or severe nocturnal hypoglycemic episodes

CGM DEVICES AND THEIR FEATURES

CGM devices have three components: a disposable subcutaneous sensor, a wireless transmitter, and a monitor that displays data. A computer is required to download, graph, and analyze the data.

Health care providers typically use the first class of FDA-approved CGM devices, which store and subsequently display data retrospectively. The second class of CGM device is designed for patient use, displaying data in real time and thereby allowing the patient to monitor and respond to personal blood glucose values in real time.

There are two FDA-approved diagnostic or professional-use CGM devices. The iPro CGMS (Medtronic Diabetes, Northridge, California) measures interstitial glucose every 5 minutes, for up to 3 days at a time. While wearing the device, the patient can record activities and

events, but the glucose values are not displayed. Glycemic information must be downloaded for retrospective review in collaboration with a health care professional.

The DexCom SEVEN PLUS CGMS (DexCom, Inc., San Diego, California) can serve as a diagnostic and a patient-use CGM device. For diagnostic use, the monitor can be set so the patient is "blinded" to the data during the collection period. When configured for patient use, the DexCom provides real-time glucose readings.

In addition to the DexCom SEVEN PLUS, there are 2 other FDA-approved patient-use or real-time CGM devices. The Guardian RT (Medtronic Diabetes, Northridge, California) displays and records real-time glucose values and allows patients to track their glucose levels and identify episodes of hypoglycemia and hyperglycemia. The Paradigm REAL-Time insulin pump and CGMS combines the Guardian RT with a Medtronic Paradigm insulin pump. The FreeStyle Navigator CGMS (Abbott Diabetes Care, Alameda, California) is also approved by the FDA for use in patients with diabetes aged 18 years and older, and a new version should be released in the second quarter of 2010. All CGM devices that are approved by the FDA are depicted and described in Table 1.

CODING FOR CGM SERVICES

There are 2 legitimate *Current Procedural Terminology* (*CPT*) codes for CGM services.

The *technical component* involves the device hookup, calibration, patient education, disconnection, and data download and may be accomplished by any qualified CGM professional. This procedure is identified by the following *CPT* code:

95250 Ambulatory CGM of interstitial tissue fluid by means of a subcutaneous sensor for a minimum of 72 hours; sensor placement, hookup, calibration of monitor, patient training, removal of sensor, and printout of recording (1).

The *interpretive component* (that is, review, interpretation, and report) is performed by a health care professional and is identified with the following *CPT* code:

95251 Ambulatory CGM of interstitial tissue fluid by means of a subcutaneous sensor for a minimum of 72 hours; interpretation and report (1).

Table 1
Continuous Glucose Monitoring Devices That Are Approved by the US Food and Drug Administration and Are Available

Application	Device name	Purpose	Features	Image
Diagnostic use (professional)	DexCom SEVEN PLUS	Professional/ diagnostic	SEVEN PLUS device that can be "blinded"	
	Medtronic iPro	Professional/ diagnostic	Small recording device with minimal patient interaction	
Patient use (personal/real time)	DexCom SEVEN PLUS	Patient use	SEVEN PLUS receiver and transmitter	
	Medtronic Paradigm/ Guardian RT	Patient use	Continuous glucose monitoring can be combined with pump or used alone	
	Abbott Navigator	Patient use	Integrated with self-monitoring of blood glucose	

CPT code 95250 was established in 2002, and *CPT* code 95251 was established in 2006. At the time the codes were created, the available technology allowed continuous monitoring for only up to 72 hours, and this time frame was incorporated into the initial code descriptions. Subsequently, however, technology for CGM has evolved, and the corresponding professional service has evolved with it. Although some sensors continue to be placed for 72 hours, others may now remain in place for 5 days or longer. For accommodation of the more durable sensors, some CGM devices can now collect and store data for longer periods. As a result, *CPT* codes 95250 and 95251 were revised in 2009 to accommodate CGM devices that store glucose readings for 72 hours or longer. In order to prevent overutilization of these *CPT* codes after this revision, instructional notes were also added to indicate that 95250 and 95251 would not be reimbursed more than once per month. Therefore, in order to qualify for reimbursement, CGM data must be collected for at least 72 hours and no more than once a month.

Another editorial change included a clarification that the use of code 95251 for the "interpretation and report" of CGM is not restricted to physicians. Other health care professionals acting within the scope of their practices (for example, nurse-practitioners and physician assistants) may also report code 95251.

KEY GUIDELINES FOR CGM CODING

- Currently, the Centers for Medicare and Medicaid Services will not reimburse personal CGM with a patient-owned device.
- The interpreting health care provider does not have to be face-to-face with the patient to report *CPT* code 95251.
- The data being interpreted must reflect at least 72 hours of monitoring.
- *CPT* code 99091 should not be used with CGM. This code describes the collection and interpretation of physiologic data collected in digital format, requiring a minimum of 30 minutes of interpretation time. This code cannot be reported in conjunction with *CPT* code 95251.
- Medicare states that services provided primarily for the convenience of a patient or provider are not medically necessary.
- Medicare states that all services reported to the Centers for Medicare and Medicaid Services must be medically necessary.
- Medicare emphasizes that claiming a noncovered service as a covered service could be viewed as fraud.

ELECTRONIC DATA REVIEW

Advances in information technology now allow a review of data from a CGM device without requiring the patient to be present in the physician's office. Using a manufacturer's specific monitor or transmitter, a patient can deliver data to a distant receiving station or secure Internet server. The analysis of the blood glucose data that are obtained remotely is identical to the data analysis during an in-office evaluation. Therefore, the interpretation and report of CGM data obtained remotely may be documented with use of *CPT* code 95251, subject to the same limitations on appropriate use that are described in the foregoing material. Whether the analysis is provided remotely or in the medical office, a report must be generated.

TYPICAL CLINICAL SITUATIONS

For the *professional-use or retrospective CGM device*, the physician typically purchases the sensor, transmitter, and monitor, as well as the workstation used to download the data to a personal computer. Under the physician's direction, an ancillary professional, such as a nurse or diabetes educator, instructs the patient regarding device calibration and use (finger-stick glucose testing, logging of meals, and recording of physical activity). The sensor is typically inserted and data collection begins while the patient is in the physician's office. After the patient has worn the sensor for a minimum of 72 hours, the patient returns to the office, at which time the sensor is removed. The data are downloaded, and a printout is obtained for review. A health care professional then interprets the downloaded data and completes a written report. The report may include an assessment of the therapeutic regimen and identification of any modifications in patient management that might be needed.

For the *patient-use or real-time CGM device*, the patient needs training in sensor placement, transmitter hookup, and monitor calibration. An ancillary professional may perform this function under the physician's supervision. After the patient has worn the sensor for a minimum of 72 hours, he or she returns to the office for instruction in sensor removal and device download. Reporting requirements are identical to those discussed in the previous paragraph. Individuals with *patient-use or real-time CGM devices* should return to the physician's office at least once to download data for physician review.

Again, in accordance with the revised codes and instructional notes, CGM must be used for a minimum of 72 hours, and codes 95250 and 95251 may be reported only once in any specific month.

INSURANCE COVERAGE FOR CGM

Within the past 12 to 18 months, many commercial insurance plans (such as Aetna, Cigna, United Healthcare, and the majority of Blue Cross/Blue Shield plans) have written positive coverage decisions for both professional and personal CGM. Because patient selection criteria and

coding criteria may vary from plan to plan, we recommend that providers verify coverage and coding idiosyncrasies directly with their payers. To reiterate, at the time of this printing, the Centers for Medicare and Medicaid Services does not reimburse for personal-use CGM.

CAVEATS REGARDING CGM INTERPRETATION

The American Association of Clinical Endocrinologists strongly advises physician supervision in the interpretation of CGM data. Current research suggests that glycemic treatment goals must be individualized for every patient with diabetes on the basis of a careful assessment of the current glycemic state, cardiovascular comorbidities, microvascular comorbidities, and hypoglycemic risk (2). The health care professional most suited to assimilate all this information and formulate a coherent diabetes treatment regimen is a physician specializing in diabetes care.

DISCLOSURE

The authors have no multiplicity of interest to disclose.

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