

Reimbursement for New Diabetes Technologies: Continuous Glucose Monitoring (CGM)

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Introduction

Reimbursement can be a confusing, frustrating process. However, as new technologies in diabetes management emerge, understanding and working with the reimbursement process will become more important than ever. This presentation looks at the process of reimbursement and issues relevant to obtaining reimbursement for continuous glucose monitoring (CGM).

Components of Reimbursement

The three components of reimbursement are coding, coverage and payment. Coding is used to classify the patient's condition, clinician services rendered and associated supplies given. Coverage relates to identifying the products and services that are eligible for payment. Payment defines the amount to be paid. Although these components are interdependent, they are three separate processes.

Current Procedural Terminology (CPT) Codes

Current procedural terminology (CPT) coding is used in all health care settings to describe physician and clinician services, laboratory tests and hospital outpatient care under Medicare. These codes are essential to clinician reimbursement.

CPT coding is controlled by the American Medical Association (AMA). To obtain coding, the professional society representing the medical specialty submits an application to the AMA. The two professional societies that represent the diabetes specialty are the American Association of Clinical Endocrinologists (AACE) and The Endocrine Society. The AMA is primarily interested in the recommendations of these organizations, and as a result, manufacturers should work closely with them to provide evidence of a given product's efficacy, safety and clinical utility and need for new CPT codes.

U.S. Food and Drug Administration (FDA) approval is a requirement and the product must be commercially available prior to submitting an application to the AMA.

It takes a minimum of 12-18 months to obtain a new CPT code for physician reimbursement. The average wait is approximately three to four years.

Once the code is granted, the AMA will survey physicians who provide the service to determine the value of the time spent utilizing the given technology or treating the specific condition. The assessed dollar value of the physician's time, practice burden and overhead is then defined as the relative value unit (RVU). The AMA then recommends the RVU to the Centers for Medicare & Medicaid Services (CMS) for determination of payment.

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Abbreviations: (AACE) American Association of Clinical Endocrinologists, (ADA) American Diabetes Association, (AMA) American Medical Association, (CGM) continuous glucose monitoring, (CMS) Centers for Medicare and Medicaid Services, (CPT) current procedural terminology, (DMEPOS) durable medical equipment, prosthetics, orthotics, and supplies, (E/M) evaluation and management, (HCPCS) Healthcare Common Procedure Coding Systems, (MNT) medical nutrition therapy, (RVU) relative value unit, (TEC) Technology Evaluation Center

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Existing Codes for Diabetes

Evaluation and Management (E/M) Codes

The majority of endocrinology treatment for diabetes falls under the E/M codes, which are based on the time and complexity involved in treating the patient. The E/M codes for an established outpatient evaluation range from 99211, the lowest reimbursement level, to 99215, the highest. It is interesting to note that almost one half of current physician E/M billing uses the 99213 code. Although clinicians often spend more time with patients and deal with more complex issues, they frequently do not bill at the higher E/M levels. One of the problems with diabetes related care is that clinicians often complain that they are not reimbursed appropriately for “cognitive services”, thus, I believe they should bill appropriately for the time and complexity of patient interaction; the greater the time spent and complexity involved, the higher the reimbursement. **Table 1** presents a description of the current billing codes for patient evaluation and management, along with two new codes that relate to CGM.

G Codes

The G codes for diabetes self management allow clinicians to bill Medicare (CMS) for diabetes educational services. However, the education program must be recognized by the American Diabetes Association (ADA) in order to receive reimbursement from Medicare. This stipulation can potentially limit access to diabetes education in areas not served by an ADA-recognized program. Another potential problem with the G codes is that they cover a limited number of hours; patients may not always receive the amount of education and training needed.

Medical Nutrition Therapy Codes

Medical Nutrition Therapy (MNT) codes allow registered dietitians or nutrition professionals to directly bill for medical nutrition therapy provided to beneficiaries with diabetes. The initial MNT benefits for diabetes include three hours of service within a 12 month period and two hours for follow-up care within that period. Although reimbursement for these services is clearly a good start in terms of providing access, the services covered may be inadequate for some individuals.

“Bundled” Codes

Other codes for diabetes therapy exist; however, they have either been “bundled” by CMS – which essentially means there is no ability to bill separately for the service and, thus, no additional reimbursement. Other codes may also exist, but no relative value has been published. Two codes for remote data transmission fall into this category which

deal with non face-to-face services and consultations (i.e. email, telephone, facsimile): These are 99090 and 99091; however, CMS has not published RVUs or established a fee schedule for these codes.

Current CPT Codes for CGM

There are two procedural codes for CGM. The first is 95250, which relate to the professional CGMS device that has been available for the past six years. This code covers the initial patient session with CGM initiation including training, device hookup, calibration, removal and data download. This code was approved in 2000 and the value has increased every year. Today, the national average for Medicare reimbursement is approximately \$156; however, private payers may reimburse higher. Although the code was originally used with the CGMS device, it is applicable to the newer CGM devices that have recently become available. Clinicians must use a code modifier (-52) if the patient brings in their own sensor because it is considered a non-expense to the physician practice.

The second procedure code, 95251, deals with data interpretation. Last year, the ACE was successful in achieving approval and valuation for 95251, which covers non face-to-face CGM data review and interpretation. Unfortunately, CMS ignored the recommended RVU for this service; the national average for reimbursement is \$29. However, ACE and CMS will revisit this payment level for 2007. Again, this code also can cover the newer devices. It should only be used once during the initial training, though the ongoing follow-up data interpretation should be covered under E/M codes if done face to face.

Healthcare Common Procedure Coding Systems (HCPCS) Codes

HCPCS codes are alphanumeric codes used to report the use of drugs, medical devices, supplies and some services (often called DMEPOS). These codes are used to classify reimbursement for insulin pumps, glucose meters and glucose test strips. Applications for new HCPCS codes for CGM devices have already been submitted.

One of the major barriers regarding HCPCS codes is the timing of applications. Applications can only be submitted on an annual basis in January and even if approved, the HCPCS code will not be effective until January of the following year. This once-per-year application cycle tends to create significant delays in getting coding and reimbursement for new technology. For example, if a company gained FDA approval for a device in October

and then launched in November, they would not have enough market data to submit an application for HCPCS coding in January. Instead, they would have to wait until the following January to submit the application, and then wait an additional year before being granted a new code. Moreover, as with other coding, obtaining HCPCS coding for a device does not guarantee coverage.

Coverage

Coverage varies by payer and plan, and differs between a national Medicare decision and a private payor. A national coverage decision by Medicare takes approximately 6 to 9 months, requiring significant clinical evidence and demonstrated demand. Private payers often use Medicare as the model for their coverage structure. However, because of the time and resources required to gain a Medicare national coverage decision, many manufacturers initially go with local Medicare coverage determinations, which can accommodate for new technologies and variation in treatment practices. For example, CGMS does not have national coverage but does have Medicare payment in all 50 states.

In lieu of coverage guidance from Medicare, private payers utilize their own methods for determining coverage. They conduct internal reviews and often refer to third-party health technology assessments such as the Blue Cross and Blue Shield Association's Technology Evaluation Center (TEC), which provides healthcare decision makers with objective and scientifically rigorous assessments of new technologies and treatments. As in many situations, private payers also listen to physicians and patients. That is why it is very important that qualified physicians work with private payers when important treatments are denied coverage.

What Will It Take To Obtain CGM Device Coverage?

The key to obtaining reimbursement for CGM devices and their utilization is publication of adequate clinical studies demonstrating positive outcomes from randomized, preferably multi-center, properly powered studies. The results should be published in respected, peer-reviewed journals. In today's health care environment, new technologies will not be covered without strong, credible scientific evidence and demonstrated need.

For diabetes care, most payers require an improvement in A1c levels as a key outcome measure. However, another important outcome that payers are just beginning to recognize is a reduction in hypoglycemic episodes. Although this metric is important to physicians and

patients—equal to or even more important than A1c—many payers do not yet fully recognize it. Clinicians, researchers and industry must do a better job of explaining to payers that reductions in hypoglycemia are important, and to emphasize the growing body of evidence regarding the impact of glycemic variability. We must focus on the outcome measures of this new CGM technology when working with payors for reimbursement. Payers are less interested in hearing about measurement accuracy alone; they want to know how the technology will impact the health outcomes of their patient population.

Another important requirement for obtaining reimbursement for CGM technology is active lobbying from clinicians and patients. Clearly, diabetes care is undervalued in the United States. Current levels of reimbursement for diabetes care and all of its complexities are inadequate and inappropriate. All of us in the diabetes treatment arena need to work collectively to advance treatment options and achieve appropriate reimbursement for new therapies. Patients, clinicians, researchers can be strong proponents and a powerful force in changing policies.

Reimbursement for Sensor-Augmented Insulin Pumps

There are numerous studies underway as well as pending publications that demonstrate the value of CGM in combination with insulin pumps. However, obtaining coverage for sensor-augmented insulin pumps such as the Medtronic Paradigm Real-Time Insulin Pump and Continuous Glucose Monitoring System is still an evolving process. At this time the insulin pump component of the system is covered but the CGM component is not covered by most payers. Encouragingly, insistence from physicians and patients has convinced some payers to cover the CGM component. In terms of clinician services, E/M coding and the procedure codes discussed earlier (95250 with modifier, 95251) apply to these devices.

Conclusion

Diabetes remains a significant and increasing burden on our healthcare system. Although new technologies create opportunities to improve diabetes care, introduction of these technologies places additional strain on our antiquated and inadequate reimbursement process. All stakeholders in the diabetes community must work collectively to improve reimbursement for these needed technologies and services. Compensation for "cognitive services" in diabetes needs to be appropriate and adequate for the services rendered. Physicians will drive these initiatives but we must ensure that non-physician health care providers continue to have a place in the process and also obtain appropriate billing opportunities.

Table 1. Current CGM Billing Codes

Code	Medicare Reimbursement (1)	Private Payer (2)
99212-99215 (E&M): Patient Evaluation <ul style="list-style-type: none"> • Comprehensive medical history • Review of past glucose monitoring • Evaluation of A1c and glucose control • Review medication regimen 	\$39 – 120	\$56 – 171
95250: Patient CGMS Initiation <ul style="list-style-type: none"> • Training • Hookup • Calibration • Removal • Download 	\$156	\$255
95251: Physician Interpretation and Report <ul style="list-style-type: none"> • Physician reviews and interprets • CGM data and generates report • Used for non-face-to-face time 	\$29	TBD

1. 2006 Medicare physician fee schedule.

This fee schedule is not geographically adjusted.

2. PMIC Medical Fees 2006. Numbers provided are 50% of usual and customary (UCR) charges