

## Reimbursement for New Diabetes Technologies: Continuous Glucose Monitoring

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### Introduction

The American healthcare system is currently geared toward management of acute illnesses. It does not effectively address the reimbursement issues and needs of chronic diseases such as diabetes. Reimbursement for patient education, cognitive services, and patient-clinician communication is inadequate. Lack of reimbursement, in turn, has an impact on the development of new diabetes technologies. This presentation looks at current trends relevant to reimbursement for continuous glucose monitoring (CGM).

### More Robust Evidence is Now Required

Healthcare payors require increasingly robust evidence before they will approve new technologies. Payors will not pay unless providers can show that utilization of a new technology such as CGM results in better outcomes. Although CGM is currently geared only toward private payors, it is also important to examine how the Centers for Medicare & Medicaid Services (CMS) views CGM because private payors often look to CMS for guidance.

#### *Centers for Medicare & Medicaid Services (CMS) Initiatives*

During the past year, CMS has put forth numerous initiatives relating to evidence development. A key focus for CMS has been clarification of its evidence requirements. This focus has been helpful to manufacturers and clinicians who need to know what CMS is looking for when it evaluates new technology. In the past there was no real agreement on how CMS evaluates various levels of evidence.

#### *Interim Reimbursement*

One new development is that CMS is now willing to consider covering new products while scientific evidence for the products is still being gathered. This is a very promising move, in spite of some problems with patient data confidentiality and other issues. CMS has recently issued guidelines regarding which technologies they think may undergo this coverage.

#### *CMS Council on Technology and Innovation*

The CMS Council on Technology and Innovation is another initiative by the agency. This initiative was mandated by the Medicare Modernization Act of 2003. Administered by two top CMS officials, it focuses on better coordinating CMS's reimbursement coverage and payment policies for new technologies.

#### *Medicare Part D Data Mining*

CMS is going to combine the data from Medicare part D with data from the part A and part B databases. This will create the largest collection of health claims data ever assembled. CMS administrator Mark McClellan, MD, has indicated that he plans to use the combined data to review claims and reimbursement for devices, hospitalizations, physician services and drugs. Based on these reviews, CMS will make comparative effectiveness and cost-effectiveness assessments of healthcare spending.

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**Abbreviations:** (CGM) continuous glucose monitoring; (CHF) congestive heart failure; (CMS) Centers for Medicare and Medicaid Services; (COPD) chronic obstructive pulmonary disease

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**Key Words:** continuous, diabetes, glucose, monitor, reimbursement

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### ***Demonstration Projects***

CMS understands the need to change the US's acute illness paradigm for reimbursement because most of the costs of Medicare programs are now attributable to chronic disease. In response to this shift in healthcare costs, CMS is implementing a number of demonstration projects in an effort to better control costs and gear the payment system toward chronic disease.

Working with disease management companies, CMS is conducting a disease management demonstration project for chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF) and diabetes. Another demonstration project will address episodes of care, which significantly affects physicians. In this project, CMS is working with 10 physician practices across the United States to look at services rendered under Medicare part A and part B. The results of this project could have significant implications for payment for diabetes care.

### ***Peer-Reviewed Literature***

In the past, it was possible to receive reimbursement without peer-reviewed outcomes evidence. However, in today's evidence-based environment, publication of scientific evidence in peer-reviewed journals is a key requirement for obtaining reimbursement.

### ***Technology Assessment***

Another evidence tool used by private payers is health technology assessments. Technology assessments are comprehensive documents based on various criteria. Because CGM technologies have received negative assessments in the past, we need to demonstrate and publish strong evidence for the clinical utility and benefits of new CGM devices in order to overturn these older assessments.

## **Changes in Payment**

### ***Pay for Performance***

CMS plans to initiate a process whereby physician reimbursement depends on performance measures. Hospitals are already being paid more for providing quality measurements, and many physicians are now also participating in voluntary programs that report quality measurements. Under the CMS plan, these performance measures will eventually impact physicians' payment rates. Current quality measurements come out of physician societies rather than a centralized system, so physician societies must be involved in the process to move to a pay-for-performance system. Many physician societies are actively engaged in measurement development.

### ***Practice Expense***

CMS held a town hall meeting in early 2006 to discuss significant planned changes to current rates of reimbursement for practice expenses. The organization is now selecting the specific amounts physicians will be paid for various practice expenses under the new plan. The changes to be made will be budget-neutral, so there will be winners and losers. Hopefully, the practice expenses that affect diabetes care will be among the winners. The proposed notice was published on July 11, 2006 and will be finalized for a January 1, 2007 implementation.

## **Roadmap to Successful Reimbursement**

The roadmap to successful reimbursement includes new and revised codes for services and products. Appropriate coding is essential. Once codes are in place, the next step is compiling credible evidence to support coverage and payment. This requires us to publish findings of clinical outcome benefits in peer-reviewed journals. In addition, we must incorporate new technologies and procedures in national clinical guidelines if they are to be widely used.

With new technology, it is not enough to simply show parity; we must demonstrate that the clinical benefit justifies higher payment and accurately reflects technological innovation. To do this, we must work with payors to determine the levels of evidence necessary for reimbursement. We must also work with private payers to update technology assessments to reflect improvements in CGM technology.

## **Conclusions**

Reimbursement for diabetes care is inadequate. This inadequacy not only inhibits the use of current therapies and interventions, it also significantly impacts the implementation of valuable new technologies such as CGM. To be successful in obtaining reimbursement for CGM, we need to coordinate activities between all stakeholders; clinician input is critical for demonstrating the value of this technology. CMS policy makers listen to and value clinician opinion regarding use of new technologies. All stakeholders must advocate for appropriate coding, coverage and payment. We need to make sure there is published evidence in peer-reviewed literature that CGM improves clinical outcomes. Clinical guidelines must be changed to reflect the utility and effectiveness of CGM.

As we develop evidence and provide input for coding and coverage, it is also important for us to support interim reimbursement. CMS has already indicated a willingness to provide interim coverage for new technologies. It is up to manufacturers, clinicians and professional associations to advocate for interim coverage of CGM.