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The Role of Reimbursement in the Adoption of Continuous Glucose Monitors

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Abstract

Continuous glucose monitors are a clinically meaningful addition to treatment plans for patients with diabetes who are actively managing their care. Since they first became commercially available, much progress has been made to ensure coverage of these devices for patients, but inadequate reimbursement of clinicians' time continues to serve as a barrier to adoption.

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Continuous glucose monitors (CGMs) are a clinically meaningful addition to diabetes treatment plans for patients who are actively managing their care, but inadequate reimbursement of the devices and of clinicians' time may be barriers to adoption. Insurance companies' decisions on whether to cover new treatments and technologies, including CGM, take into account a number of factors and have an effect on all their members. In addition to covering and paying for the CGM devices for patient use, insurers also reimburse the health care team who treats patients with diabetes and helps them manage their care. Provider payment for diabetes care is already inadequate, and the addition of CGM to patients' care may prove to be financially untenable.[1] Reimbursement challenges for CGM exist within the larger context of reimbursement for diabetes care as a whole. Diabetes care, in turn, is part of a wider national debate on how to reform the health care system. When thinking about ways to improve the reimbursement environment for CGM, it is important to consider both the product- and disease-specific issues and to look to the future and the broader context of health reform. While some reimbursement obstacles for CGM access have been removed, there is still more that can be done.

When discussing reimbursement, most people think of whether an insurer pays for a product or service. While payment is an essential piece of the reimbursement puzzle, the whole picture is more complex, involving issues of coverage and coding. A favorable reimbursement environment across coverage, coding, and payment is necessary for patients to have ready access to the treatments and technologies they need. Insurance companies face the difficult task of balancing their members' somewhat conflicting desires for coverage of treatments and services with low premiums and out-of-pocket cost sharing. Any additions to what a plan covers affect the premiums they charge, whether it is a high-cost device only a handful of members need or a moderately priced treatment used by a large number of patients. Payers are

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Abbreviations: (CGM) continuous glucose monitor, (FDA) Food and Drug Administration, (JDRF) Juvenile Diabetes Research Foundation

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constantly evaluating new treatments across a broad range of illnesses and must determine if they are appropriate for their members (and if so, which subset of members). Among the questions they face are how to operationalize this coverage within their claims processing systems—whether the necessary codes exist to describe the product or treatment in question, the diseases indicated, and the procedures necessary to deliver or perform the treatment—and determining what is an appropriate payment for the treatment or product. If all these pieces do not fall into place, it is often difficult or impossible for patients to have access to innovative treatments.

Continuous glucose monitors are an example of a potentially transformative treatment whose adoption initially suffered because of an unfavorable reimbursement environment. The Food and Drug Administration (FDA) approved the first CGM device for patient use in 2005,[2] but until recently, insurance companies have not broadly covered or paid for CGMs. This lack of coverage is likely due to the devices receiving FDA approval as an adjunctive therapy to standard home blood glucose monitors. Since CGMs are an additive rather than a replacement therapy, they are also an additive cost for payers who are already covering blood testing meters and strips.

As FDA approval is necessary but not sufficient for reimbursement, insurers have required more data on clinical effectiveness before covering CGMs for patient use. The studies available when CGMs for patient use first became commercially available showed that the devices gave readings of glucose in interstitial fluid at regular intervals with an acceptable level of accuracy, meeting the standards for FDA approval. The few studies published demonstrating the benefits of CGMs over discrete finger stick blood glucose testing were relatively small[3] and short.[4] Payers were already covering blood glucose monitors and test strips for their members with diabetes, and compelling data did not exist to show that adding CGMs would help improve patient outcomes. Insurance companies determined that the evidence base was not adequate to justify the added expense of CGMs. Given the high number of people with diabetes that insurance plans cover, none were willing to extend broad coverage of CGMs to their members without more specific data on the benefit of CGMs. During this time, plans would evaluate requests from members for CGM coverage on a case-by-case basis to determine if coverage was appropriate for that individual, a long and labor-intensive process.

The Juvenile Diabetes Research Foundation (JDRF), a patient-funded research organization, recognized the need to assess the effectiveness of these new technologies and help patients gain access to them. As part of its Artificial Pancreas Project,[5] JDRF designed and funded a study[6] that sought to answer payers' central question: How do CGMs compare to conventional treatment modalities in helping patients with diabetes reach their treatment targets? The JDRF trial met the needs of insurance companies for several reasons. First, it was a rigorously conducted, randomized control trial. Second, it was not being funded by any of the CGM device manufacturers, allaying most fears of inherent bias in the research. Finally, it was conducted over a sufficient period of time to indicate whether the use of CGMs could have a sustained effect on patients' diabetes management. The results of the JDRF trial have been instrumental in convincing insurance companies to expand their coverage policies for CGMs for a subset of their members with diabetes. Aetna, CIGNA, UnitedHealthcare, WellPoint, Kaiser Permanente of Northern and Southern California, and other major payers have since broadened their CGM-coverage policies citing the JDRF study.[7–11] These plans account for more than 120 million covered lives, meaning many more patients are now able to afford and use these devices; however, there are still some reimbursement obstacles. Current policies often delineate a certain subset of type 1 patients who are eligible for CGM coverage, such as for those 25 years of age and older or those who experience recurrent, severe hypoglycemia. In addition, Medicare does not cover CGMs for its beneficiaries, stating that it is considered "precautionary."[12–15] Medicare's decision is presumably due to the FDA labeling for these devices as adjunctive to finger stick testing and the lack of data on the efficacy of CGMs in patients 65 years and older.

Despite these obstacles, many more patients now have access to CGMs because their insurer has made a favorable coverage decision. These coverage policies are essential for patients to have access to CGMs since they do not have to pay the full out-of-pocket cost for the device and supplies. As with any treatment or technology, insurers typically apply cost sharing for plan members, meaning they must pay a portion of the cost of a drug or device in order to access it. While some patients may have difficulty with the cost sharing imposed by their specific insurance policy—this is not an issue specific to CGMs or diabetes treatments—it bears watching, as one mechanism insurers employ to impede access is to impose more onerous cost-sharing requirements on their members.

While reimbursement to cover the cost of the CGM device and related supplies is essential to adoption, it is not the only factor. Changing a patient's treatment regimen and their subsequent management is a significant effort on the part of clinicians. This effort on the part of providers is vital, as a key to patient success with CGM is proper training on how to use the device and data they receive to enhance their ability to manage their diabetes. Continued lack of adequate reimbursement for physicians, nurses, and certified diabetes educators is also a barrier to widespread adoption of CGMs. In order for patients to have access to CGMs, their doctor has to be willing to prescribe it. The number of providers who are comfortable using CGMs and are able to afford to add it to their practice will be directly impacted by the level of reimbursement for patient care paid to clinicians by insurers.

Helping patients with chronic illnesses like diabetes manage their care does not fit well within the system of reimbursement for provider services. Providers receive payment for face-to-face interaction with patients and for performing procedures, but between-visit phone calls, emails, and other "virtual" interactions do not typically result in payment. This already poses a problem for physicians, certified diabetes educators, and other practitioners who care for people with diabetes, as patients and caregivers routinely have questions for their health care team between regular office visits. The introduction of a CGM may only compound the problem, as the number of between-visit questions that patients have will likely increase as they have more data to decipher. Providers will be faced with more data to analyze at and between visits but will not see an increase in the amount they are paid for taking care of these patients. A key to patients improving their diabetes management with CGMs is using the data these devices provide to make treatment adjustments. If their health care team cannot afford to spend the necessary time with them to make these adjustments, patients may not reap the full benefits. While many providers will find a way to make this work, others will continue to be unwilling or unable to find a viable financial model to include CGMs in their patients' treatments, thus limiting access.

In light of broader health reform being in the national spotlight, it is important to keep in mind the lessons learned to date from CGM reimbursement. Current discussions of what health reform is or should be are vast but often include the need for better models of chronic care.[16] In addition, there is a growing focus and awareness on the need to address the diabetes epidemic in the United States. The challenges of optimizing CGM reimbursement—gathering credible data to show clinical benefit and ensuring that clinicians are paid appropriately for the time they spend caring for patients—are illustrative of the larger challenges inherent to diabetes care. The path to securing reimbursement for CGMs can serve to highlight larger issues in diabetes care, such as assessing new treatments for coverage, particularly as the number of treatment options expand. In addition, the difficulty with integrating CGMs into clinical practice is a concrete example of the struggle health care providers face in finding the right balance between providing high-quality care and keeping their practices financially viable. As health reform discussions take shape, it is essential that diabetes stakeholders are active participants and use their experience with CGM reimbursement to help frame the current problems with the system and propose potential solutions.

The reimbursement environment for CGMs is not simply about covering the devices. Restrictive coverage policies and cost-sharing requirements from insurance plans may be prohibiting even those individuals who have insurance coverage from accessing CGMs. Further, physicians may be unwilling or unable to prescribe CGM if they cannot afford the level of care necessary to manage patients using this treatment. Despite these obstacles, many patients do have coverage for CGMs and are able to work with their health care team to integrate it into their self-management plan. Many of the reimbursement-based barriers to CGM adoption have already disappeared; however, work remains to ensure providers receive adequate payment for their time, effort, and expertise.

Disclosure:

Both authors have worked as consultants to the Juvenile Diabetes Research Foundation.

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