



**ManagedCareCGM.com Presents:**

# **DIABETES QUALITY MANAGEMENT**

**Trends and Opportunities for Continuous  
Glucose Monitoring in Managed Care Pharmacy**

**Academy of Managed Care Pharmacy 2024  
Annual Meeting Satellite Symposium**

**Payer IMPACT Brief**

# The Role of CGM in an Expanding Treatment Paradigm Including GLP-1 Utilization

## Timothy Gilbert, MD

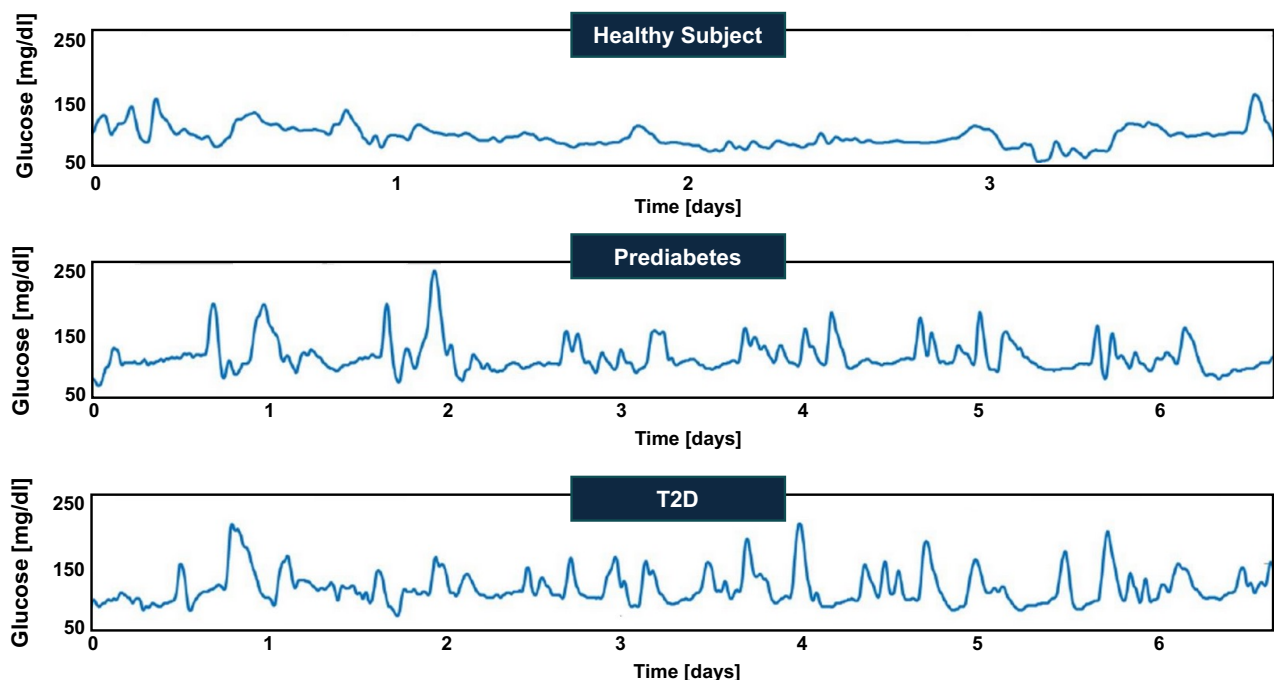
Clinical Endocrinologist  
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Diabetes is associated with a myriad of complications and comorbidities, substantially impacting both individuals and the health care system. Effective management involves a combination of lifestyle adjustments, medication adherence, monitoring, education, and support. The expanding use of continuous glucose monitoring (CGM) has been transformative in diabetes care, providing valuable real-time data and insights for better management. At the same time, the introduction of innovative therapeutics, such as incretin mimetics and specifically glucagon-like protein-1 receptor agonists (GLP-1s) are helping patients achieve improved outcomes. Dr. Timothy Gilbert, a clinical endocrinologist at Imperial Health, discussed these and other topics pertinent to modern diabetes management using a preventive medicine approach.

Evidence continues to emerge showing the clinical relevance of glycemic variability and its role in the pathophysiology of cardiometabolic disorders. In diabetes, the variability in the occurrence of glucose “spikes” and their magnitude delineate the disease course progression from glucose intolerance/prediabetes to type 2 diabetes (T2D).<sup>1</sup> According to Dr. Gilbert, “As diabetes progresses, you see much more glycemic variability. The glucose profile looks like an earthquake tracing. It’s a lot of shaking going on, and all that shaking leads to bad things.” Specifically, postprandial hyperglycemia is a key marker in the development of T2D and is characterized by glucose spikes after meals.<sup>2,3</sup> Assessing how often patients spike, the duration of the spikes, and the area under the curve are all vital in effectively detecting prediabetes and mitigating its progression to T2D. In fact, detecting and addressing glycemic variability as early as possible is the only way to truly change the course of diabetes from the outset. In addition to their role in the progression of T2D, postprandial glucose spikes and glycemic variability are also indicative of cardiovascular risk. Hyperglycemia and glucose variability result in decreased vasodilator effect, which can contribute to hypertension. The resulting endothelial dysfunction also contributes to adhesion in the bloodstream and the formation of atherosclerotic plaques.<sup>4,5,6</sup>

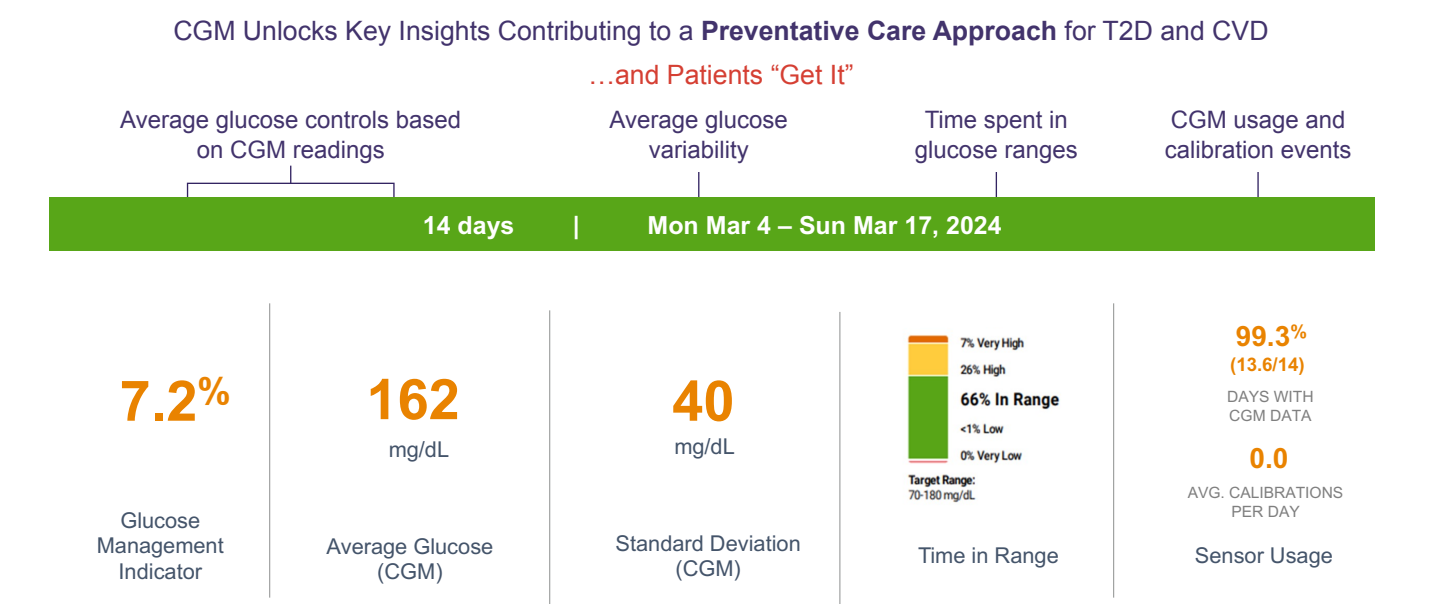
*In addition to their role in the progression of T2D, postprandial glucose spikes and glycemic variability are also indicative of cardiovascular risk.*

## Glycemic Variability and “Spikes” Delineate the Clinical Course of Diabetes



The Role of Continuous Glucose Monitoring (CGM) in High-Quality Diabetes Management

While HbA1c offers a snapshot of diabetes management at one static moment in time, only CGM can provide a detailed picture of glycemic variability. As a result, CGM unlocks key insights that can contribute to a preventive care approach for both T2D and cardiovascular disease (CVD). In this manner, CGM can be most impactful early in the clinical course of any dysglycemia, when intervention has the potential to be preventative. Dr. Gilbert noted, “Diabetes will not kill you. It will be the heart attack, the stroke, the renal failure, or the hypoglycemic event. So, we control the variables. We can do that better now that we’re able to continuously monitor glucose values in at-risk patients.”




Battelino T, et al. Diabetes Care. 2019;42(8):1593-1603. Beck RW, et al. Diabetes Care. 2019;42(3):400-405.

In addition to the clinical utility of CGM, patients are able to comprehend CGM-specific measures such as time in range (TIR). Providing individuals with diabetes a visual representation and tangible goals via CGM reports offers an opportunity for patient engagement and behavior change, which results in improved outcomes.<sup>7,8</sup> Recognizing these benefits, the American Diabetes Association (ADA) and other leading professional organizations support the clinical utility and value of CGM. In its 2024 Standards of Care, the ADA cites Grade A evidence in recommending CGM be offered to individuals with diabetes and used in individuals at high risk of hypoglycemia.<sup>9,10,11</sup>

Mounting Evidence Supporting CGM Use in Broader Populations

The body of evidence supporting CGM use has grown to the point that little distinction is made regarding diabetes type or treatment regimen: the potential for improved outcomes and real-world value exists across diverse populations of patients, including those affected by comorbidities. Among 47 patients enrolled in a CVD outpatient program, CGM use was associated with improved glycemic and cardiometabolic outcomes.<sup>12</sup> In the 2-phase crossover study, participants were



**“We’re able to achieve reductions in HbA1c with a CGM that has no side effects. It just engages the patient. And we’re doing that for a cost that is significantly lower than any of our branded medications on the market.”**  
- Timothy Gilbert, MD

required to have T2D not treated with insulin therapy, an HbA1c >7%, and an obesity classification (BMI ≥30 kg/m2). Through 90 days of follow-up, CGM use was associated with a reduction in average glucose (184.0 to 147.2 mg/dL, *P*<0.001), an increase in time in range (57.8 to 82.8%, *P*<0.001), and a trend towards lower glycemic variability (26.2% to 23.8%). CGM users also experienced significant reductions in HbA1c, body mass index (BMI), triglycerides, blood pressure, total cholesterol, diabetes distress, and 10-year predicted risk for atherosclerotic CVD (*P*<0.05 for all).

Similarly, CGM demonstrates improvements in a host of glycemic outcomes regardless of age. In a real-world study, more than 6,000 CGM users with non-insulin-treated (NIT) T2D were followed using the CLARITY software interface.<sup>13</sup> In just 6 months, results showed improved glycemic outcomes post-initiation of CGM in terms of mean glucose, glucose management indicator (GMI), coefficient of variability (CV), TIR, time below range (TBR), and time above range (TAR) compared to pre-initiation. These improvements were observed among patients aged ≤65 years as well as among those aged ≥65 years.

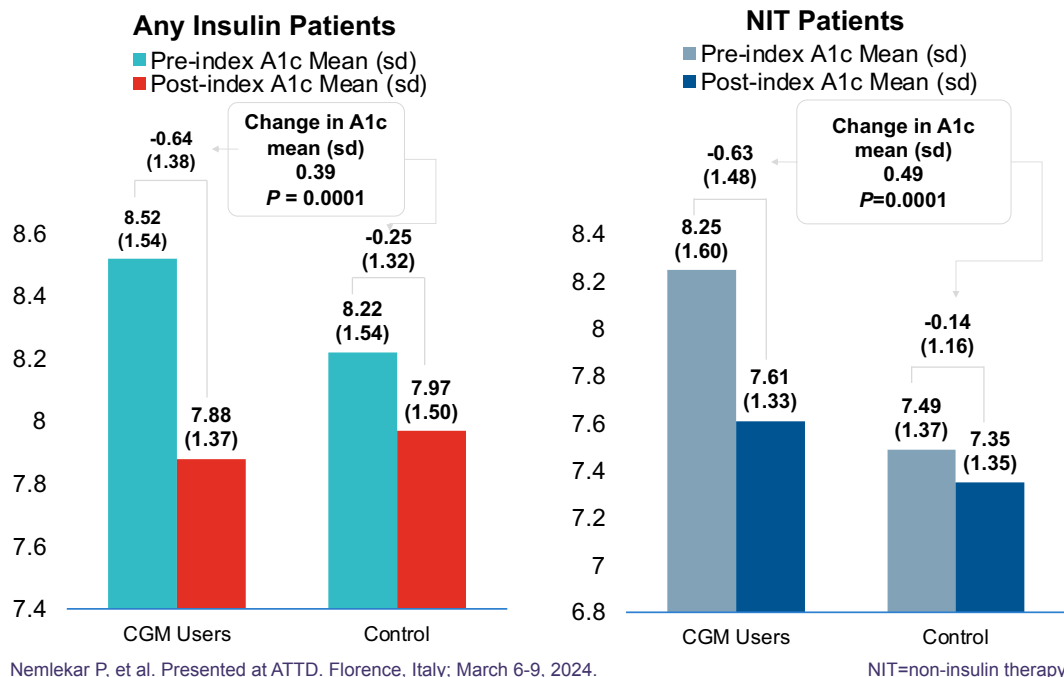
In addition to short-term trials showing the benefit of CGM in T2D regardless of treatment regimen in terms of glycemic outcomes, a long-term study demonstrated a reduction in mortality associated with CGM in a Veterans Affairs (VA) population.<sup>14</sup> In this first-of-its-kind study, the researchers retrospectively analyzed claims data from the VA Health Care System and noted a 47% reduction in mortality risk among T1DCGM users (n=7,513) and a 14% reduction in T2D CGM users. CGM users (n=7,513) and a 14% reduction in T2D CGM users. Along with mortality, CGM initiation was associated with a reduction in the risk of hypoglycemia-related emergency events, risk of hyperglycemia events in T2D, and all-cause hospitalization.

## The Complimentary Benefits of CGM With Incretin Mimetics

CGM can play a vital role in the management of diabetes with the incretin mimetic class and specifically GLP-1s. Data are showing that CGM use increases after initiation of a GLP-1, indicating a perceived complimentary benefit among clinicians. This trend is occurring among patients with T2D treated with insulin as well as among those not treated with insulin.<sup>15</sup> Both insulin and GLP-1s are associated with increased risk of hypoglycemia, so individuals treated concomitantly with these agents are particularly vulnerable to hypoglycemic events. Similar to its use in other patients at increased risk of hypoglycemia, prescribing CGM for these individuals can be beneficial as a risk-mitigation strategy. At the same time, CGM can help monitor the effect of behavior modification and lifestyle changes among individuals with NIT T2D and enhance patient engagement. In addition to increased risk of hypoglycemia, there is a lack of clear clinical guidance for initiating GLP-1 therapy among individuals already treated with insulin. Current challenges associated with GLP-1 therapy contribute to 50% of users discontinuing treatment in the first year and 70% discontinuing within 2 years.<sup>16,17,18,19</sup> Collecting real-time glucose data with CGM can help fine-tune GLP-1 and insulin use, avoid hypoglycemia, and improve therapeutic persistence.

In addition to increasing the safety and efficiency of GLP-1 utilization, CGM can enhance the glucose-lowering benefit of GLP-1s when used concomitantly. In an analysis of data from more than 57,000 GLP-1 users with insulin-treated and NIT T2D, both cohorts of patients who also used CGM demonstrated greater mean reductions in HbA1c (-0.39 and -0.49 for insulin-treated and NIT T2D, respectively;  $P=0.0001$ ).<sup>20</sup> These data show that CGM and GLP-1s are both vital components of a comprehensive strategy to improve diabetes management in clinically appropriate groups of patients with insulin-treated and NIT T2D. Furthermore, Dr. Gilbert pointed out that this synergistic benefit may allow for deprescribing other therapies: "I can't tell you how many patients, when they come in, are on metformin, they're on a sulfonylurea, and they're on a basal insulin. And within a few months, we're able to eliminate the sulfonylurea and we're able to eliminate the basal insulin using GLP-1s and CGM. We would not be able to ween them off the insulin as quickly and as safely as we do without the use of CGM."

### Emerging Evidence Suggests HbA1c Lowering From a Combination of GLP-1 and CGM



# What’s New in HEDIS Measures for Quality-Driven Diabetes Care?

**Maureen Hennessey, PhD, CPCC, CPHQ**  
SVP, Director of Value Transformation  
PRECISIONvalue

The management of diabetes in the United States is suboptimal, with less than one-third meeting the ADA-recommended HbA1c target of <7%.<sup>21</sup> Health plan performance in diabetes management according to current quality measures is likewise mediocre. Looking specifically at the National Committee for Quality Assurance’s (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS) measures for HbA1c control (<8%) and poor HbA1c control (>9%), performance is lagging, particularly in the Medicare and Medicaid lines of business.<sup>22</sup> According to Dr. Maureen Hennessey of PRECISIONvalue, “It’s disturbing when we look at commercial Medicaid and Medicare plans, we see easily a quarter and even as many as 40% of individuals are experiencing inadequate control. We still have a long way to go.”

Despite this current lack of quality performance in diabetes management, there are numerous studies demonstrating the benefit of CGM in established HEDIS and other quality measures, including HbA1c, health care resource utilization, and patient experience/quality of life.<sup>23</sup> This evidence has been published in the form of randomized controlled trials, open label extensions, and real-world evidence. Dr. Hennessey added, “I’m hopeful because we do have data now that show that when we use CGM, populations begin to meet or improve their performance on HbA1c targets. Health care utilization and costs and quality of life are also favorably impacted by the use of CGM.”

The Evidence Documents CGM-Driven Improvement in HEDIS and Other Diabetes Quality Measures

| Quality Metrics                |   |
|--------------------------------|---|
| HbA1c Targets                  | Increase in % HbA1c <8.0%   |
|                                | Decrease in % HbA1c >9.0%   |
| Healthcare Utilization & costs | Decrease in diabetes-related or all-cause ED visits and/or hospitalization and/or costs |
| Quality of Life                | Reduced diabetes distress   |
|                                | Improved hypoglycemia confidence  |
|                                | Reduced worry/fear of hypoglycemia  |
|                                | Greater well-being  |
|                                | Improved diabetes-related QoL   |
|                                | Improved sleep quality  |
|                                | Improved hypoglycemia attitudes & behaviors   |
| Treatment Satisfaction         | Reduced stress/anxiety  |
|                                |   |

Expanded use of CGM provides an opportunity to modernize quality measurement by leveraging advanced metrics for assessment of glycemic status, diabetes quality improvement, and population health tracking



## The Advantages and Limitations of HbA1c

HbA1c is the diabetes measure that nearly every payer is familiar with, and it meets all the standards for a “good” quality measure.<sup>24, 25</sup> It is useful and can be leveraged to achieve quality goals. HbA1c is also reliable and valid as well as understandable by stakeholders, making it useful for decision-making. Finally, HbA1c is feasible as a measure in that it can be obtained as part of clinical care. However, HbA1c also has a number of inherent limitations, both as a quality measure and a guide for disease management. Although HbA1c remains a mainstay of diabetes measurement, it is static in nature and offers only a narrow perspective on diabetes management. Furthermore, HbA1c can be impacted by a number of factors:<sup>26</sup>

- Hemoglobinopathies
- Iron deficiency
- Chronic kidney disease (CKD)
- Liver disease
- Individual changes in red blood cell lifespan
- Unknown genetic factors affecting glycation
- Race
- Age

These limitations can impact diabetes quality management, specifically among individuals affected by social determinants of health (SDOH). For example, on average, HbA1c levels overestimate the mean glucose in black persons compared with white persons, possibly owing to racial differences in the glycation of hemoglobin.<sup>27,28</sup>

## Leveraging Technology in Evolving Diabetes Quality Measurement

Diabetes quality measures are evolving as organizations recognize CGM’s advantages over HbA1c monitoring for

guiding management decisions, patient engagement, and lifestyle modification. In their whitepaper, “Rethinking Diabetes Care in the Digital Age,” NCQA outlines the necessary evolution of quality measures to include technology and more sophisticated measures such as TIR and GMI.<sup>29</sup> Reductions in HbA1c



**“From a social determinants of health perspective, CGM is very empowering, particularly for certain populations or subpopulations. And to take it a step further, NCQA now has been very concerned about race, ethnicity, health disparities, with 22 of their measures now stratified by race and ethnicity.”**  
- Maureen Hennessey, PhD, CPCC, CPHQ

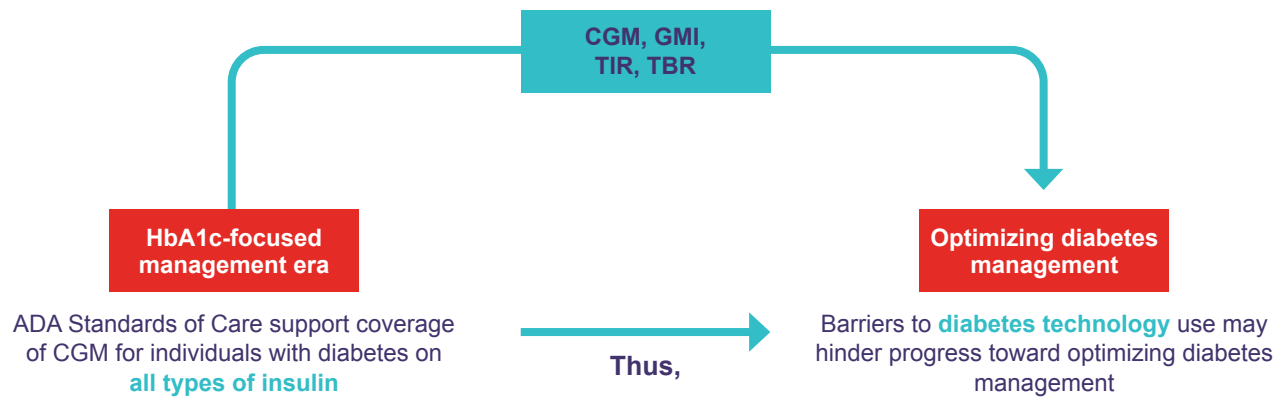
*Reductions in HbA1c have long been tied to improved clinical outcomes, but data have been emerging showing the same relationship with increased TIR.*

have long been tied to improved clinical outcomes, but data have been emerging showing the same relationship with increased TIR. Specifically, reduced TIR has been linked to worsening clinical outcomes such as albuminuria, retinopathy, peripheral neuropathy, abnormal carotid intima-media thickness,

CV mortality, and cardiac autonomic neuropathy.<sup>30,31,32,33,34,35,36,37,38</sup> GMI is calculated from an equation that translates mean glucose from CGM into an estimated HbA1c value but overcomes some of the limitations of a single, static HbA1c measurement.<sup>39</sup>

While HbA1c is a mediocre diabetes management metric and a good quality measure, the CGM-derived TIR metric represents an excellent diabetes management metric and an evolving quality measure. Dr. Hennessey noted, “HbA1c is a good measure, but alone, it’s not working. We have large numbers of individuals within populations right now that are not at goal. We’re seeing the field change quality measures and standards. They’re evolving to include CGM to achieve more optimal diabetes management.” Other CGM-derived metrics such as GMI—which was recently adopted as a HEDIS quality measure—help bridge the gap between HbA1c measurement and the diabetes technology era. Specifically, the former “HbA1c control for patients with diabetes” measure was revised to “glycemic status assessment,” which is a measure that accounts for either GMI or HbA1c.<sup>40</sup> GMI is a measure that only CGM can provide, and NCQA is accepting the automatic reporting of GMI from CGM software in lieu of HbA1c data, which must be collected and reported by physicians’ offices and hospital personnel. Additional changes to the HEDIS measures for 2024 include continued focus on SDOH, with race and ethnicity stratification for eye exam and kidney health evaluation measures. Glycemic status assessment is likewise stratified by race and ethnicity.

## Quality Measures and Standards Are Evolving to Include CGM to Optimize Diabetes Management



*GMI=glucose management indicator; PA=prior authorization; TBR=time below range; TIR=time in range.*

Adapted from R. Bergenstal presentation materials - Digital Quality Summit, July 2021.

NCQA. 2021. Accessed August 9, 2023. <https://www.ncqa.org/white-papers/rethinking-diabetes-care-in-the-digital-age/>

### The Future of Diabetes Quality Measures

HbA1c and GMI are two widely adopted metrics for gauging the effectiveness of diabetes management, but additional CGM-derived measures are anticipated to emerge in the future. Dr. Hennessey noted several considerations that managed care and payer decision makers should be mindful of as the landscape continues to evolve. The first was the possible emergence of a process measure to assess the use of CGM, stratified by race and ethnicity, to identify disparities in access. Also related to race and ethnicity, Dr. Hennessey mentioned the potential development of regression equations to account for scenarios in which GMI and HbA1c differ across different races and ethnicities. The eventual incorporation of TIR, TBR, and TAR into measure sets was the final future consideration presented, with Dr. Hennessey noting that GMI is likely only the first of several. As additional metrics are added, payers have an opportunity to leverage technology to improve care quality by minimizing barriers to CGM access. Dr. Hennessey concluded, "I really encourage all of you to begin to think about how you can further evolve your organization's use of CGM to help improve performance in diabetes quality measures."

# Health Plan Best Practice Update on CGM Coverage, Access, and Real-World Value

## Susan Wescott, RPh, MBA

Senior Director of Pharmacy  
Managed Care Mayo Clinic

## Sean Chitwood, PharmD, MBA

Clinical Pharmacist, Medicare Stars & Clinical Quality  
Optum Rx

To understand the opportunity for health plans to support improved patient outcomes with CGM, the Academy of Managed Care Pharmacy (AMCP) and Impact Education, LLC, sponsored a multifaceted approach to identify best practices consisting of expert interviews, a national payer survey, an expert panel workshop with clinical experts and managed care stakeholders, and a national webcast to communicate the program findings.<sup>41</sup> Susan Wescott, RPh, MBA, Senior Director of Pharmacy at Managed Care Mayo Clinic, participated in the initiative and shared the health plan best practices in CGM access and coverage that were identified:

*To understand the opportunity for health plans to support improved patient outcomes with CGM, AMCP and Impact Education, LLC, sponsored a multifaceted approach to identify best practices consisting of expert interviews, a national payer survey, an expert panel workshop with clinical experts and managed care stakeholders, and a national webcast to communicate the program findings.*

- Provide coverage under the pharmacy benefit
- Implement utilization management with automated adjudication at the point of sale
- Develop processes to identify and address underserved and other at-risk populations
- Provide clinician and patient education and engagement
- Monitor data to assess the reduction in healthcare resource utilization

## The Community Glucose Monitoring Project

As an update to the 3-month data shared in the best practices workshop, 6-month follow-up findings from the Community Glucose Monitoring Project were also shared. A clinic in Ohio leveraged a relationship with managed Medicaid plans and a local Fortune 500 company to provide CGM to patients with T2D regardless of treatment regimen, with no utilization management or restrictions on access. At this most recent follow-up, data from 237 CGM users were assessed and demonstrated a 2.3% reduction in HbA1c from baseline ( $P < 0.001$ ).<sup>42</sup> In addition, the proportion of participants who met the HEDIS HbA1c target of  $< 8.0\%$  increased from 18.6% at baseline to 82.7% at the 6-month follow-up. The study lead, Dr. Thomas Grace, also noted some anecdotal findings at the 6-month follow-up, specifically:



**“With CGM, we’re seeing greater reductions in HbA1c than we do by adding a drug. These patients’ lifestyle choices have contributed to their condition. So how do we learn as humans, how do we change our behavior? A feedback loop from CGM is super helpful in doing that.”**

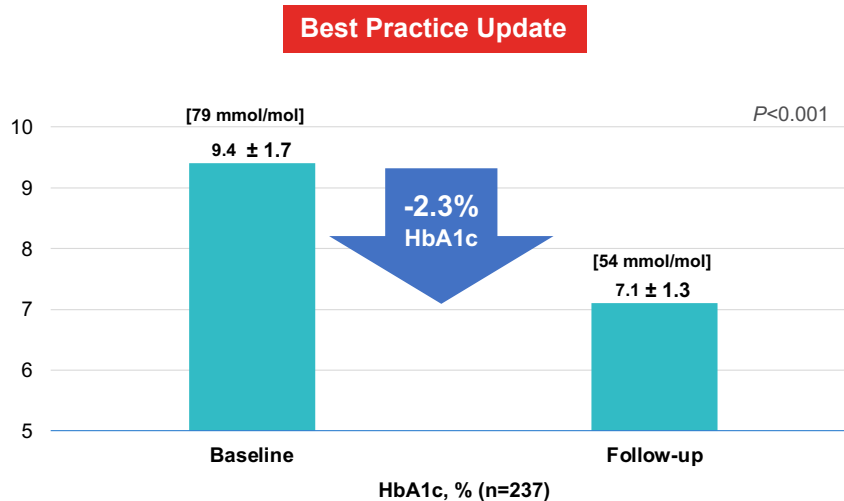
- Susan Wescott, RPh, MBA

- CGM helped adjust and deprescribe some T2D medications.
- CGM was able to be initiated with minimal clinician oversight.
- CGM should be considered early in diabetes care.
- CGM does not have dose-limiting toxicity concerns.

Interestingly, the improvements in glycemic outcomes seen in the Community Glucose Monitoring Project could be tied back to behavior modification, as shown by a subset of participants who were interviewed ( $n=34$ ).<sup>43</sup> All of the interviewees reported marked changes in their diet, 32% reported increased physical activity, and 26.5% reported greater medication adherence. In addition, many mentioned that CGM increased their confidence, interest, and engagement in managing their T2D.



## Community Glucose Monitoring Project 6-month Follow-up: Background and **Change in HbA1c**



Grace T, et al. *Clin Diabetes*. 2024; In Press.

### **CGM and Medicare Stars Quality Ratings**

Sean Chitwood, PharmD, MBA, Clinical Pharmacist, Medicare STARS & Clinical Quality at OptumRx, provided insights from on quality measurement from the Medicare Advantage perspective. Medicare Advantage Plans are graded on a 1 to 5 “star” rating by the Centers for Medicare and Medicaid Services (CMS), and the plans receive a bonus payment of 5% if they reach 4 stars overall. Customer or member experience is a very important aspect of Medicare Star ratings, in addition to traditional clinical quality metrics. In 2021, CMS doubled the weight of the member experience rating for Medicare STARS, so that one-third of a Medicare Advantage payer’s star rating was impacted by member experience and access to care.<sup>44</sup> Therefore, improved performance in clinical measures and member satisfaction/access to care can result in real-world savings for health plans that often invest in specific technologies to garner cost offsets through the STARS program. In this manner, there is an opportunity with CGM to impact multiple HEDIS, adherence, and Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures. As of 2021 the CAHPS survey for Medicare feeds into Stars measures that are 4x weighted, and those member experience measures will comprise the largest component of plans’ overall ratings, underscoring the importance of access to care and patient satisfaction.<sup>45,46</sup>

### **Emerging Evidence Demonstrating the Value of CGM in Quality Measure Performance**

Given the increased focus on SDOH and race/ethnicity stratification in quality measure sets, several studies have emerged showing the benefits of access to CGM in disadvantaged populations. In a Medicaid population of more than 3,000 beneficiaries, subsidized access to CGM resulted in significant improvements in A1c across different racial/ethnic groups, including a 1.2% reduction in those with T2D.<sup>47</sup> Overall, those with higher fill adherence to CGM achieved greater HbA1c reduction (–1.4% vs. –1.0%;  $P < 0.001$ ). Similarly, broader access to CGM under the pharmacy benefit improved



**“In addition to improving measure performance related to HbA1c and member experience, CGM offers an opportunity to improve fill adherence. Interacting with a pharmacist to consult on CGM offers an extra provider contact and enhances patient accountability.”**

- Sean Chitwood, PharmD, MBA

outcomes in an ethnically diverse employee population from Metro Nashville Public Schools, regardless of insulin treatment type (N=184; T1D, n=43; T2D, n=141, 40% NIT T2D).<sup>48</sup> The school district covered CGM through the pharmacy benefit with no prior authorization and saw a 2-fold increase in utilization. Improvements in clinical outcomes aligned with current quality measures followed, as there was a 41% increase in the number of individuals achieving the

HEDIS HbA1c target of <8.0%. In addition, there was a 67% increase in the number of individuals achieving the ADA-recommended A1c target of <7.0%.

## Broader Access to CGM Under the Pharmacy Benefit Improved Outcomes In an Ethnically Diverse Population

No prior authorization required

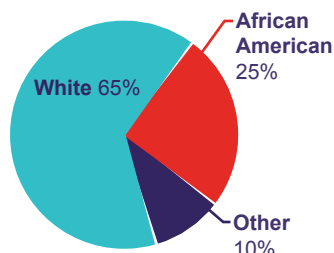


**2-fold** Increase in CGM utilization

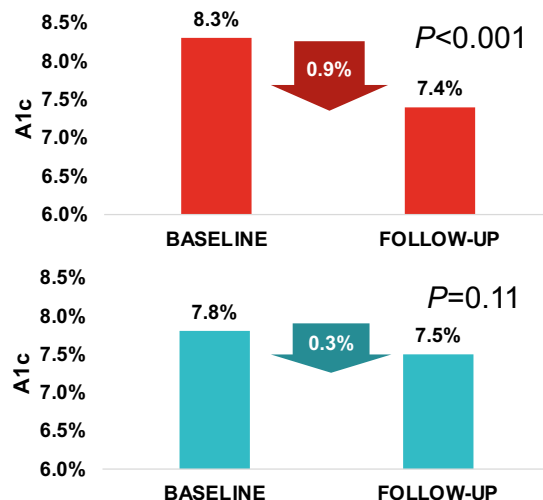
**41%** Increase in the number of individuals achieving the HEDIS A1c target of <8.0%

**67%** Increase in the number of individuals achieving ADA A1c target of <7.0%

Race



Improvement in A1c (pre/post CGM)



\* $P < 0.01$ . American Diabetes Association; HEDIS=Healthcare Effectiveness Data and Information Set. Thomas R, et al. Abstract presented at AMCP 2024; New Orleans, LA; April 15-18.

Further data show that CGM improves outcomes in alignment with quality measures related to kidney function and eye health, in addition to reducing resource utilization. A retrospective analysis of US administrative claims data included patients with T2D, using insulin, not receiving dialysis, and living with stage 3-5 CKD who initiated CGM between January 1, 2016, and March 31, 2022 (N=8,959).<sup>49</sup> After CGM initiation, hospitalization rates for hyperglycemia or hypoglycemia decreased by 18.2% and 17.0%, respectively ( $P < 0.0001$  for both). The proportion hospitalized with at least one hypoglycemic or hyperglycemic event also significantly decreased after CGM initiation. Looking specifically at eye health, the COMISAIR 7-year follow-up evaluated 84 insulin-treated patients with T1D treated with multiple daily injections or insulin pump therapy.<sup>50</sup> In addition to resulting in significantly lower HbA1c than blood glucose monitoring regardless of insulin delivery method, CGM use was also associated with a lower incidence of diabetic retinopathy at 7-year follow-up despite a higher incidence at baseline. Dr. Chitwood put these cumulative findings into perspective: “With CGM we’re seeing improvement across the board. Reducing retinopathy, reduced hospital use. These are important to health plans because there are associated costs and there are STARS measures you’re being graded on.”

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