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UNVEILING THE LATEST EVIDENCE: CGM'S EVOLVING IMPACT ON DIABETES CARE

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Current State of Diabetes Care Quality

Diabetes is a major health crisis in the United States (US) with an estimated 38 million people currently affected¹ and projected increases in incidence and prevalence through 2050.² Avoidable and consequential diabetes–related morbidity and mortality result in substantial costs to both the health care system (\$307 billion) and society (\$106 billion).³ Type 2 diabetes (T2D) accounts for about 90% of all diabetes cases with most individuals treated with basal insulin only (BI) or noninsulin therapy (NIT).^{4,5}

Despite significant progress made in developing more effective options for managing and treating diabetes, ⁶ including remarkable advances in continuous glucose monitoring (CGM) technology,⁷ controlling T2D remains an ongoing challenge. Data from 2023 demonstrate that depending on type of insurance, 30%-49% of patients fail to achieve Healthcare Effectiveness Data and Information Set (HEDIS)–defined glycemic control (HbA_{1c} < 8%), and an additional 22%–40% have HEDIS–defined poor glycemic control (HbA_{1c} > 9%).¹⁸ CGM offers an opportunity for health plans to improve their HEDIS score and the Centers for Medicare & Medicaid Services (CMS) Five–star Quality Rating, which is heavily influenced by members' ratings of their experiences and access to care.⁹

CGM has become the standard of care for patients with type 1 diabetes (T1D) and T2D on intensive insulin therapy (IIT)¹⁰⁻¹³ based on a strong body of high–quality clinical evidence showing that CGM reduces HbA_{1c}, improves time in range (TIR), and reduces hypoglycemia across a wide age range and regardless of insulin delivery modality in these populations.^{14–29} However, CGM is not routinely accessible to the vast majority of patients with diabetes—those with T2D on BI or NIT—who are often poorly controlled and at risk for costly and serious acute and long–term diabetes complications. The purpose of this review is to summarize current and emerging evidence demonstrating the value of CGM for this large population. Expanding access

to CGM in this population would address a significant unmet need and has the potential to dramatically reduce the clinical and economic burden associated with uncontrolled diabetes in the US.³⁰

Technological Advancements in CGM

Over the past 25 years, innovations in CGM technology have resulted in a transformative tool to improve diabetes management.⁷ There have been major technological advances in interstitial glucose-sensing technology, including decreased sensor size, increased convenience and accuracy, elimination of the need for calibration with fingerstick blood glucose monitoring, approval of nonadjunctive status, and improved data and device interoperability as part of automated insulin delivery (AID) systems.⁷ Currently marketed CGMs, such as the Dexcom CGM System, are indicated for use in patients 2 years or older, provide highly accurate measures of glucose levels and real-time remote data-sharing capabilities; and notify patients of impending severe hypoglycemia via an Urgent Low Soon alert. Dexcom G7 is the only CGM system that can connect directly to the Apple Watch, eliminating the need to carry an iPhone to view glucose levels and trends. Users can receive and acknowledge alerts and alarms on their Apple Watch, providing added flexibility and reduced burden of diabetes in everyday life.

Growing Body of Evidence for CGM Use in Insulin-Treated Type 2 Diabetes

Findings from two landmark studies—the MOBILE randomized controlled trial (RCT)³¹ and the Karter et al observational study³²—support CGM as the standard of care in patients with insulin–treated T2D, including those on BI.³³

The MOBILE trial was the first US RCT to evaluate CGM in adults with T2D on BI.³¹ The 8–month study randomly assigned 175 ethnically and socioeconomically diverse adults treated in

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primary care settings to CGM or traditional blood glucose monitoring (BGM). Patients treated with CGM had a significant reduction in HbA_{1c} (-1.1% from baseline and -0.4% versus BGM), improvement in TIR (3.6 more hours/day), and reduction in time above range (TAR; 3.6 fewer hours/day), and a lower rate of hypoglycemic events (-0.1 events/week) compared with BGM. In the CGM group, 63% of participants met the HEDIS quality measure of HbA_{1c} <8% compared with only 39% using BGM. The clinical benefits of CGM were seen across all patient subgroups, including race, age, education, diabetes numeracy, socioeconomic status, and baseline HbA_{1c}.^{31,34} Findings from MOBILE demonstrate that CGM yields similarly strong glycemic benefits in patients with T2D receiving less intensive insulin regimens as has been reported in clinical trials and real-world studies of T2D patients who require more intensive insulin regimens.33 The MOBILE trial also shows that CGM is an effective treatment for racial and ethnic minorities and low-income persons with T2D who have disproportionately experienced poor diabetes health outcomes and faced barriers to full access to health care and health-care-related technology.35

The effectiveness of CGM in the real world has matched or exceeded RCT results for insulin-treated individuals with T1D and T2D. A real-world study conducted by Kaiser Permanente of Northern California used a propensity score-matched cohort analysis to compare CGM and BGM (12 months pre/post-CGM initiation) among members with insulin-treated T2D (n=36,080).³² CGM resulted in a 0.56% reduction in HbA_{1c} compared with +0.09% for BGM. Of note, the HbA1c benefit of CGM in members with T2D (-0.56%) was at least equal to that in members with T1D (-0.34%). The proportion of patients achieving the HEDIS quality measure of HbA_{lc} < 8% increased by 17.7% and the proportion with poorly controlled diabetes (HbA₁>9%) decreased by 10.8% in patients treated with CGM. In addition, CGM initiation halved the rate of emergency department (ED) visits and hospitalizations for hypoglycemia. Thus, this study confirmed that CGM yields superior glycemic control under usual care conditions for a broad group of T2D patients and reduces resource utilization by avoiding ED visits and hospitalizations. A subanalysis of the Kaiser claims data in 149 people with well-controlled T2D (HbA_{1c} <8% at baseline, no history of severe hypoglycemia) showed that CGM initiation resulted in a 0.06% reduction in HbA_{1c} vs a 0.3% increase in HbA_{1c} for BGM.³⁶ The difference between CGM and BGM resulted in a net benefit of -0.3% HbA_{tc} associated with

CGM initiation and demonstrates the value of CGM in preventing glycemic deterioration among individuals with already acceptable glycemic control.

CMS Announces Expanded Coverage of CGM for Medicare Beneficiaries

In March 2023, based on the growing body of evidence supporting the effectiveness of CGM in patients with T2D, CMS announced expanded coverage of CGM for Medicare beneficiaries.¹³

Expanded Coverage of CGM for Medicare Beneficiaries

The CMS policy update, effective April 2023, expanded eligibility requirements for CGM to include patients using any insulin regimen or patients not on insulin, but with a history of problematic hypoglycemia.



In addition, the policy dropped the requirement that CGM users perform fingerstick glucose checks. Expanding access to CGM is an important step in optimizing glycemic management, achieving diabetes goal performance measures, and promoting improved outcomes in patients with diabetes.³⁷⁻³⁹

Clinical Practice Guidelines Recommend CGM in Type 2 Diabetes

2023

In 2023, the American Diabetes Association (ADA),³⁷ American Academy of Clinical Endocrinologists (AACE),³⁸ and Endocrine Society³⁹ published updated guidelines for the use of CGM in clinical practice. Changes to the guidelines called for broadening the use of CGM in patients with T2D and ensuring continued access to CGM.

According to the ADA 2023 Standards of Care, CGM *should* be offered for diabetes management in adults with diabetes who are being treated with BI (Grade A Evidence).³⁷ Furthermore, per the AACE Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm (2023 Update), CGM is highly recommended for persons with T2D to safely reach glycemic goals.³⁸ The

Endocrine Society, in their clinical practice guidelines, has stated "We suggest CGM be used rather than no CGM for outpatients with type 2 diabetes who take insulin and/or sulfonylureas and are at risk for hypoglycemia."³⁹

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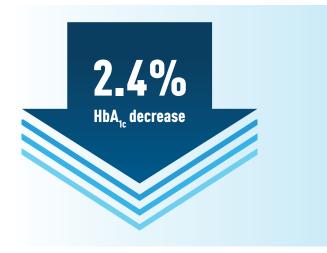
In late 2023, the ADA released the 2024 Standards of Care in Diabetes. The ADA generalized their recommendations for CGM, stating that "diabetes devices should be offered to people with diabetes (Grade A Evidence),"10 underscoring their commitment to expanding the availability of CGM devices to patients with T2D. The 2024 Standards of Care state "use of CGM is beneficial and recommended for individuals at high risk for hypoglycemia (Grade A Evidence),"¹⁰ which recognizes the benefit of CGM in reducing hypoglycemic episodes. The ADA recommends assessing glycemic status by HbA₁₀ and/or appropriate CGM metrics at least two times a year and more frequently (eg, every 3 months) for individuals not meeting treatment goals who have frequent or severe hypoglycemia or hyperglycemia, changing health status, or growth and development in youth.¹⁰ The ADA expanded the section on CGM in pregnancy, advocating for its use in pregnancies associated with T1D and promoting personalized approaches to CGM utilization for pregnant individuals with T2D or gestational diabetes, considering treatment regimens, circumstances, preferences, and needs.⁴⁰

Emerging Evidence for CGM Use in Non-Intensively Treated Type 2 Diabetes

Although most people with T2D are treated in primary care settings, CGM is often underutilized in primary care. Real–world evidence is growing to support the use of CGM in primary care to improve clinical outcomes in T2D patients. In a real–world study, 237 CGM–naive T2D patients treated with BI or NIT and



In CGM-naive T2D patients, the proportion of participants who met the HEDIS HbA1c target of < 8.0% increased from 18.6% at baseline to 82.7% at 6-month follow-up.



who lacked insurance coverage for CGM were provided a Dexcom CGM at no cost.⁴¹ After 6 months of CGM use, HbA_{1c} decreased by 2.4% (P<0.0001) and TIR increased by 28.7%, which was largely attributable to a time in tight range (TITR) increase of 25.8%. This study demonstrated that initiation of CGM in adults with T2D on less intensive regimens without the oversight of an endocrinologist was associated with improved glycemic control.

Recent studies have demonstrated the benefits of Dexcom CGM in adults with T2D NIT. A real–world study analyzed CGM data over 6 months from 6641 NIT T2D adult patients who had baseline TIR \leq 70%.⁴² Both younger (< 64 years) and older (\geq 65 years) cohorts experienced an increase in TIR (15.8% and 13.3%, respectively). The proportion of users meeting TIR >70% increased from 0 to 39.2% and 0 to 31.9% in the younger and older cohorts, respectively. The overall reduction in GMI was 0.5%. Use of CGM was associated with an increase in TIR and a clinically meaningful decrease in GMI in NIT T2D adults.

Both HbA_{1c} and CGM metrics, such as TIR, are well correlated with diabetes complications. TIR is associated with major adverse cardiovascular events, severe hypoglycemia, and microvascular events in people with T2D.⁴³ RCTs and real–world studies have shown that CGM can improve TIR without increasing time above range (TBR) in people with T2D NIT.⁴⁴ CGM–derived TIR is a good metric to track the risk of complications and CGM metrics (TIR and TBR) have the most potential to motivate and facilitate action. There are a variety of strategies to increase the effectiveness of CGM in the T2D NIT population, including using a high–alert setting and continuing to move this setting down as progress is made. Research has shown that

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Emerging Evidence for CGM Use in Non-Intensively Treated Type 2 Diabetes







Benefits of Addressing Barriers to Access Through the Pharmacy Channel





Reduction in Health Care Resource Utilization and Mortality





https://tinyurl.com/39dy8pme







CGM users with T2D NIT who maintained or adjusted the CGM high–alert setting achieved higher TIR and TITR than users who disabled this setting, with the best outcomes seen in patients who maintained or lowered their high–alert setting.⁴²

HEDIS Diabetes Measures Introduce Key Changes Reflecting New Diabetes Management Strategies

In 2023, the National Committee for Quality Assurance (NCQA) updated the HEDIS Quality Measures to include ED visits for hypoglycemia in older adults with diabetes.⁴⁵ NCQA also introduced the new measure—Social Need Screening and Intervention (SNS–E)—developed as part of an organization—wide effort to advance health equity and encourage health plans to assess and address the food, housing, and transportation needs of their patient populations.⁴⁵

In 2024, changes were made to two existing HEDIS measures.⁴⁶ The NCQA revised and renamed the measure "Hemoglobin A1c Control for Patients With Diabetes" to "Glycemic Status Assessment for Patients With Diabetes." The Glycemic Status Assessment now allows the use of either HbA_{1c} or the glucose management indicator (GMI), which is calculated using CGM-measured mean glucose, as an option to meet the numerator criteria (ie, HbA_{1c} <8% and HbA_{1c} <9%). The GMI estimates what an individual patient's approximate HbA_{1c} level is likely to be, based on the average glucose level from the patient's CGM readings for 14 or more days.⁴⁷ This change aligns with the 2024 ADA Standards of Care which recommends the use of CGM metrics in assessing glycemic status. In clinical practice, it is advised that GMI and other CGM-derived metrics be used with laboratory-based HbA_{1c} to personalize diabetes management.^{47,48}

In addition, as part of its effort to identify and reduce disparities in care, the NCQA introduced race and ethnicity stratifications to nine additional HEDIS measures in 2024, including Kidney Health Evaluation for Patients With Diabetes and Eye Exam for Patients With Diabetes.⁴⁶

Benefits of Addressing Barriers to Access Through the Pharmacy Channel

Barriers to widespread and equitable CGM use are the policies surrounding appropriate insurance coverage. A policy change to the Blue Cross Blue Shield of North Carolina (Blue Cross NC) formulary in December 2018 greatly expanded access to these therapies by reducing prior authorization (PA) requirements and making coverage for CGM available through the pharmacy channel for nearly all insulin–using Blue Cross NC members with diabetes.⁴⁹ This policy change resulted in an increase in CGM use from 18.8% and 1.2% among T1D and T2D patients, respectively, to 58.2% and 14.9%, respectively. In addition, CGM initiation was associated with a 14% lower incidence of ED visits in patients with insulin–treated T1D and T2D.^{49,50} These findings underscore the potential health care and economic benefits of increasing access to CGM among insulin–treated people with diabetes.

Increasing access to CGM through policy options, such as adding CGM to the pharmacy channel, may be an important part of promoting equitable uptake of evidencebased technology by reducing barriers to access faced by lower income or lower health literacy patients.



Utilization management criteria associated with this policy restricted coverage to patients with diabetes who use insulin. Increased CGM use in this population aligns with those whom clinical guidelines suggest would most likely benefit. CGM underutilization in typically underserved demographics of minority patients can be addressed via enhanced member access by making coverage available through the pharmacy channel and removing manual PAs.

KEY TAKEAWAY: Efforts to improve access to CGM will help meet quality measures and address underutilization of CGM among disproportionately affected members.

Reduction in Health Care Resource Utilization and Mortality

Recently published real-world studies add to the growing body of evidence demonstrating that CGM adoption significantly improves glycemic control, reduces the incidence of diabetes-related acute complications requiring emergency health care and all-cause hospitalizations, and reduces mortality in people with insulin-treated T1D and T2D.⁵⁰⁻⁵²



Patients with diabetes and chronic kidney disease (CKD) are at heightened risk of glycemic variability which could lead to hypoglycemic or hyperglycemic crises.⁵³ A retrospective analysis of US admin-

istrative claims data evaluated whether initiation of CGM could reduce the incidence of hospitalizations for patients with insulin–treated T2D and moderate–to–severe CKD.⁵¹ After CGM initiation, rates of hospitalizations for hyperglycemia or hypoglycemia decreased by 18.2% and 17.0%, respectively (*P*<0.0001 for both). This analysis of real–world data suggests that CGM initiation may help people with T2D and CKD maintain glycemic control and avoid serious glycemic excursions that result in hospitalization.

A large retrospective observational cohort study within the Veterans Affairs Health Care System identified patients with insulin-treated T1D or T2D who initiated CGM between January 2015 and December 2020.⁵⁴ HbA, hypoglycemia-or hyperglycemia-related admission to the ED or hospital, and all-cause hospitalization were assessed 12 months before and after CGM initiation. At 12 months, declines in HbA1c (difference in differences) were significantly greater in CGM users with T1D (-0.26%; 95% confidence interval [CI]; -0.33, -0.19%) and T2D (-0.35%; 95% CI; -0.40, -0.31%) compared with non-users. CGM initiation was associated with a significantly reduced risk of hypoglycemia emergency events (hazard ratio [HR] 0.69; 95% CI; 0.48, 0.98) and all-cause hospitalization (HR 0.75; 95% CI; 0.63, 0.90). In patients with T2D, there was a reduction in the risk of hyperglycemia emergency events in CGM users (HR 0.87; 95% CI; 0.77, 0.99) and all-cause hospitalization (HR 0.89; 95% CI; 0.83, 0.97).

A continuation of this study compared total mortality between propensity score weighted initiators of CGM and non–CGM users on insulin (n = 46,066) over 18 months.⁵² Risk for mortality was 47% and 14% lower, respectively, in T1D CGM users (HR: 0.53, 95% CI; –0.43, –0.65) and T2D CGM users (HR 0.86, 95% CI; 0.76, 0.97) than in non–users over 18 months. In this large national cohort, initiation of CGM was associated with sustained improvement in HbA_{1c} in patients with later–onset T1D and patients with T2D using insulin. This was accompanied by a clear pattern of reduced risk of admission to an ED or hospital for hypoglycemia or hyperglycemia, all–cause hospitalization, and mortality.

KEY TAKEAWAY: CGM may have broad-based benefits that extend beyond glucose lowering in patients with diabetes on insulin.

Real-World Studies Show CGM Reduces Costs

A retrospective analysis of US health care claims data identified 790 commercially–insured people with T2D who used CGM while treated with IIT and evaluated changes in diabetes–related hospitalizations and health care resource utilization costs after initiation of Dexcom CGM.⁵⁵ During the 12 months after CGM initiation, the number of diabetes–related inpatient visits was reduced by 50%, resulting in an average savings of \$330 per member per month (PMPM), primarily driven by reductions in hospitalizations for hyperglycemia and ketoacidosis. Real-World Studies Show CGM Reduces Costs





https://tinyurl.com/3bey7526



Dexcom CGM initiation among patients with T2D IIT significantly reduced diabetesrelated inpatient hospitalizations (50%), ED visits (47%), and costs associated with hospitalization, medication, and health care resource utilization.

Two earlier studies also reported a significant reduction in health care costs associated with CGM initiation in people with T2D. In a retrospective analysis of administrative claims data, average baseline diabetes-related health care resource utilization costs were -\$424 PMPM (P=0.035) during \geq 6 months of follow-up after people with T2D initiated CGM.⁵⁶ Intermountain Healthcare conducted a prospective randomized study in primary care clinics and found

participants using Dexcom CGM over 6 months experienced a significant decrease in HbA_{1c} (-0.6%, P = 0.001), total visits (P = 0.009), ED encounters (P = 0.018), and labs ordered (P = 0.001) as compared with the BGM group.⁵⁷ This resulted in a



CGM Adherence Drives Greater HbA1c



Sustained Use of CGM









https://tinyurl.com/3zum6tda





https://tinyurl.com/36wk7m6u

Expanding CGM Use



https://tinyurl.com/6yhmcz4p



https://tinyurl.com/2p99ht3m







\$417 PMPM cost savings for SelectHealth participants and \$426 PMPM for Medicare Advantage members.

KEY TAKEAWAY: CGM initiation resulted in a >\$400 PMPM cost savings for members with T2D.

CGM Adherence Drives Greater HbA₁, Change

A retrospective study of a large US administrative health claims database examined the relationship between adherence to CGM, reductions in HbA₁₋, and type of CGM device in patients with T1D or T2D treated with IIT.58 Patients using Dexcom real-time CGM (rtCGM) were more adherent than those using intermittently-scanned CGM (isCGM). The average proportion of days covered was 71% (T1D) and 72% (T2D) for rtCGM users and 55% (T1D) and 56% (T2D) for isCGM users. The odds of adherence were more than two times higher for rtCGM versus isCGM users for patients with T1D (odds ratio [OR] 2.8; 95% CI; 2.4, 3.3; *P*<0.0001) and T2D (OR 2.2; 95% CI; 1.9, 2.5; *P*<0.0001).

Adherence was shown to drive improvement in HbA₁₋. Adherent CGM users achieved significantly greater HbA1c improvements compared to nonadherent CGM users (T1D: -0.51% [-0.9% vs -0.39%); T2D: -0.34% [-0.93% vs -0.59%]). Among adherent users with T1D or T2D, 69.8% and 66.1% met the HEDIS target of HbA_{1c} <8% at follow–up, respectively, whereas only 45.7% and 45.5% of nonadherent users with T1D or T2D, respectively, met this goal.

KEY TAKEAWAY: Adherent CGM users achieved significantly greater HbA_{1c} improvements compared to nonadherent CGM users.

Sustained Use of CGM is Associated With Lower **Risk of Diabetic Retinopathy**

An estimated 9.60 million Americans (26.4%) suffer from diabetic retinopathy (DR).⁵⁹ On average, it costs about \$600 to \$1000 a year per patient to manage diabetic eye disease,60 and diabetes-related blindness costs total more than \$500 million per year.⁶¹

Groundbreaking research has proven that CGM reduces the risk of DR.62 Preliminary results from the COMISAIR-7 study suggested that approximately twice as many patients on BGM had newly diagnosed or progressive retinopathy compared to those on CGM after 7 years.⁶³ More recently, a retrospective cohort study of 550 adults with T1D in a tertiary diabetes center and ophthalmology center from 2013 to 2021 found that CGM use reduces the risk of developing DR and progressive diabetic neuropathy.62



KEY TAKEAWAY: These outcomes demonstrate the durability of effect and potential of CGM to lower the risk of long-term diabetes complications.

Expanding CGM Use in Special Populations

On December 8, 2022, the Dexcom G7 was the first CGM to be cleared by the FDA for use in women living with diabetes during pregnancy.⁶⁴ The G7 is safe and accurate without confirmatory fingerstick testing during pregnancies complicated by diabetes (T1D, T2D, gestational diabetes).65 The %20/20 agreement rate with blood glucose values in the 63-140 mg/dL range was 92.3%, which is similar to the 95.3% agreement rate seen in nonpregnant adults with diabetes.66 Dexcom G7 sensors were well tolerated in all trimesters of pregnancy and no serious adverse events occurred.

New data contribute to the growing body of literature demonstrating that CGM is effective across race and treatment regimens. A retrospective study evaluated changes in HbA_{1c} and CGM initiation in 941 patients with T2D stratified by insulin therapy and race/ethnicity.⁵¹ After CGM initiation, an overall mean reduction in HbA₁₀ of 0.79% (P<0.001) was observed with similar reductions seen across all race/ethnicity groups and therapy regimens (IIT, BI, and NIT). These findings indicate that CGM can be an effective treatment for populations who have historically experienced disparities in access to CGM and are at a higher risk for diabetes-related complications.



KEY TAKEAWAY: CGM can be an effective treatment for populations who have historically experienced disparities in access to CGM and are at a higher risk for diabetesrelated complications.

Utilization of GLP-1 Agonists in Conjunction With CGM Improves T2D Outcomes

A retrospective analysis of US claims data (2019-2021) assessed trends in HbA1c change during the 12 month pre- and post index from CGM initiation in people with T2D on glucagon-like peptide-1 receptor agonists (GLP1-RA) stratified by any insulin or NIT.⁶⁷ Cohorts based on insulin therapy regimens using GLP1–RA but not using CGM served as control groups. In this sample of \approx 58,000 people with T2D on GLP1–RA, those who used CGM experienced a significantly greater decrease in HbA_{1c}, irrespective of insulin treatment (any insulin: –0.4% difference in differences, *P*<0.0001; NIT: –0.5% difference in differences, *P*<0.0001). The study suggests that initiating CGM in people with T2D on a GLP1–RA may be associated with a reduction in HbA_{1c}, regardless of insulin usage.

A qualitative study evaluated the role of Dexcom CGM in diabetes management in 26 people with T2D on BI therapy, including 11 patients on GLP1–RA.⁶⁸ TIR was 90% for GLP1–RA–using participants versus 74% for non–GLP1–1RA participants. CGM helped visualize the favorable impact of BI on glucose, improved participants' perceived control and engagement with diabetes, allowed therapy optimization specifically around BI dosing, and improved understanding of the impact of changing comorbid conditions on participants' glucose.

KEY TAKEAWAY: Dexcom CGM may enhance patient understanding and management of T2D, including those on GLP1–RAs.

Conclusions

Despite substantial evidence documenting the clinical and economic benefits of CGM, most patients with T2D across all treatment regimens are not utilizing this technology.49 The adoption of CGM is enhanced when impediments to access are removed. This review of the growing body of evidence documenting the benefits of CGM use among people with T2D treated with basal insulin or noninsulin regimens advocates for expanding access to CGM to a broader T2D population including vulnerable groups who are disproportionately affected by diabetes.³⁰ Evidence strongly indicates that wider use of CGM should reduce short- and long-term diabetes complications that place an enormous burden on patients, caregivers, and the health care system. Increased implementation and expanded use of CGM should improve clinical outcomes and reduce diabetes-related health care costs.



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