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Health Care Stakeholder Summit

WHITE PAPER

Leveraging Diabetes Health Technology in Managed Care:

Coverage Considerations for Real-Time Continuous Glucose Monitoring from the Therapeutic CGM Stakeholder Summit

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KEY TAKEAWAYS

- While A1C remains an important measure in clinical decision making, it fails to capture acute glycemic excursions and the magnitude and frequency of intra- and interday glucose variation.
- The advent of continuous glucose monitoring (CGM) has allowed for more comprehensive targets in clinical practice, including time in range (TIR).
- Real-time CGM (rtCGM) systems automatically transmit glucose information and alerts and alarms without patient intervention, including while the patient is sleeping.
- rtCGM in real-world practice demonstrates reductions in A1C and hypoglycemia while increasing TIR, with improvements in humanistic and economic outcomes such as quality of life (QoL) measures, hypoglycemic fear, treatment confidence, and health care resource utilization.
- Pharmacy coverage for CGM represents a more streamlined approach, with automated utilization management, real-time adjudication and claims approval, and streamlined member access at the community pharmacy.
- Pharmacy benefit coverage provides cost savings for health plans via lower acquisition costs, rebates, and patient access to guideline-endorsed technology, which can improve outcomes and decrease health care resource utilization.

EXECUTIVE SUMMARY

Diabetes remains a significant driver of morbidity, mortality, and cost in managed care despite perpetual advances in treatment. Although the clinical and economic benefits of stringent glycemic management are well documented, the majority of patients fail to achieve adequate management, and imprecise attempts to reach glycated hemoglobin A1C (A1C) goals contribute to deleterious and costly micro- and macrovascular complications associated with hypo- and hyperglycemia. Additionally, patient fear of hypoglycemia and lack of education and engagement exacerbate these issues, resulting in further inadequate treatment and reduced quality of life (QoL).

As more comprehensive knowledge of the disease and advances in health technology emerge, new glycemic targets centering on time in range (TIR) and time above/below range are being prioritized. Owing to the potential for more precise glycemic measurement due to the advent of continuous glucose monitoring (CGM), these markers demonstrate advantages over A1C in that they provide a more accurate portrayal of daily variability in glucose levels. Additionally, CGM addresses the limitations of traditional modalities for self-monitoring of blood glucose (SMBG) by capturing a wealth of patient data on a regular basis. While intermittently scanned CGM (isCGM) needs to be purposely scanned by the patient to obtain glucose information, real-time CGM (rtCGM) systems automatically transmit glucose information and alerts and alarms without patient intervention. Furthermore, rtCGM systems automatically provide up to 288 measurements in a 24-hour period, including while the patient is sleeping. The clinical and economic benefits of rtCGM utilization have been extensively published in the literature, demonstrating reduced A1C, improved TIR, fewer hypoglycemic events, reduced health care resource utilization, and increased workplace productivity.

Despite being recommended in consensus guidelines and endorsed by a number of professional organizations, some current payer benefit design schema and utilization management interventions may hinder patient access to CGM. In addition, payers may not be cognizant of evolving outcomes measures and glycemic targets in diabetes care, impeding the implementation of appropriate plan management strategies. Restrictive prior authorization (PA) criteria under the medical benefit and the PA process itself have been identified as barriers to access among patients and a source of administrative burden for providers. Conversely, coverage of CGM under the pharmacy benefit alleviates these inefficiencies and provides a more seamless experience for providers and patients alike, enhancing prescribing and access. For payers, CGM coverage under the pharmacy benefit offers automated utilization management via step edits and likewise reduces administrative burden. Furthermore, CGM coverage across both benefits is typically at least cost neutral, and coverage under the pharmacy benefit often results in cost savings for payers due to rebates/contracting and administrative efficiencies. Factoring in the potential for improved outcomes and reduced health care resource utilization via the avoidance of hypoglycemic episodes further compounds the value of enhanced access to CGM.

To discuss these and other considerations for the advancement of evidence-based, precision diabetes management leveraging health technology, the *Therapeutic CGM Health Care Stakeholder Summit* convened a panel of payer and employer leadership with clinical experts in the field of endocrinology. Clinical evidence supporting the clinical and economic value of rtCGM was presented, and the insights of these health care stakeholders were captured en route to formulating coverage policy recommendations for the future.

INTRODUCTION

The clinical and economic impact of diabetes on the US health care system is undeniable, ranking among the top 10 conditions in terms of prevalence, mortality, and total cost.[1,2,3] There are more than 30 million Americans living with diabetes at an estimated cost of >$327 billion per year.[3] Pharmacologic therapies for the management of diabetes drive the traditional drug trend, and the cost to treat the complications associated with diabetes alone totals $44.1 billion per year.[3,4] In addition to the direct bearing of diabetes on clinical outcomes, its role in cardiovascular (CV) and renal syndromes compounds the cumulative burden of the disease, which may be underestimated by the overgeneralization of primary diagnosis codes and idiopathic sequelae.

Although it remains plagued largely by inadequate outcomes, the management of diabetes has advanced significantly over the course of the past 3 decades, with more sophisticated forms of insulin, new molecular targets in pharmacotherapy, and emerging health technology interventions.[5] Recognizing these advancements, professional organizations and governing bodies have adopted the latest evidence-based medicine into clinical practice guidelines and recommendations. Among them, therapeutic continuous glucose monitoring (CGM) has established its place in the contemporary diabetes management armamentarium, at the cusp of the dawning era of personalized medicine and true precision care.

Recognizing the significant opportunity and potential pitfalls of this nascent revolution in the chronic disease management paradigm, the *Therapeutic CGM Health Care Stakeholder Summit* brought together key opinion leaders from regional and national payers with leading clinicians in endocrinology to share their perspectives and facilitate the uptake of evidenced-based medicine and health technology in diabetes management.

CURRENT GAPS IN DIABETES MANAGEMENT AND CLINICAL PRACTICE

Despite more than a century of burgeoning knowledge and continual advancements in the field of endocrinology, the management of diabetes remains largely suboptimal. Less than a third of insulin-using patients achieve the American Diabetes Association (ADA) glycated hemoglobin (A1C) target of <7%; instead, the A1C goal for insulin users is only met by 31% of patients, and the average A1C of type 1 diabetes (T1D) patients is 8.4%.[6,7]

The landmark Diabetes Control and Complications Trial (DCCT, 1982–93) and the Epidemiology of Diabetes Interventions and Complications (EDIC, 1994–2006) study provided remarkable insights into the importance of tight glycemic control. These findings showed, via extensively followed cohorts, that 30 years of excellent versus poor glycemic control substantially reduced microvascular complications and the incidence of the following:[8] retinopathy requiring laser therapy (5% vs. 45%), end-stage renal disease (ESRD; 0% vs. 5%), clinical neuropathy (15% vs. 50%), myocardial infarction (MI; 3% vs. 5%), stroke (0.4% vs. 2%), and death (6% vs. 20%). The economic and humanistic implications of excellent glycemic control were also apparent, with $90,900 in averted costs due to complications per participant and a gain of ~1.62 quality-adjusted life years (QALYs).[8]

However, achieving optimal outcomes in diabetes management extends far beyond glycemic control. While it is crucial to maintain A1C and blood glucose levels under guideline-recommended thresholds, hypoglycemia bears a significant disease burden of its own, in T1D and insulin-treated type 2 diabetes (T2D) patients alike. Having been labeled as the "greatest limiting factor in diabetes management," hypoglycemia affects virtually every organ system and can therefore result in remarkable morbidity and mortality.[9] The very nature of these episodes can result in a self-propagating phenomenon known as hypoglycemia-associated autonomic failure (HAAF), in which hypoglycemia causes both defective glucose counter-regulation and impaired awareness of hypoglycemia (IAH), making it increasingly difficult for patients to recognize the signs and symptoms of hypoglycemic episodes.[9] For this reason, the risk of hypoglycemia is pervasive among those who have previously experienced non-severe hypoglycemic events (NSHEs) or severe hypoglycemia (SH) and those with IAH, a condition affecting as much as 40% of T1D patients with a lower prevalence in T2D patients treated with insulin.[10] In addition, risk of hypoglycemia is also high in pediatric/adolescent and elderly demographics of insulin-treated patients with T1D and T2D, among others.

"More than 50% of hypoglycemic events occur at night when patients aren't checking their blood sugar."

– Provider Representative

CURRENT GAPS IN DIABETES MANAGEMENT AND CLINICAL PRACTICE (CONTINUED)

The occurrence of hypoglycemia in patients with insulin-treated T1D or T2D can have a significant effect on health care resource utilization, morbidity, and mortality. Across 15 Phase 3a studies, 536 severe hypoglycemic events among T1D and insulin-treated T2D patients were analyzed. Of these episodes, 157 enlisted ambulance transport (29.3%), 64 involved emergency department (ED) visits (11.9%), and 36 required hospital admission (6.7%). Although there were fewer events in people with T2D compared with T1D, once a severe episode occurred, the tendency to utilize healthcare resources was higher in T2D versus T1D.[11] Furthermore, insulin—a surrogate marker for the impact of hypoglycemia on health care resource utilization—is the second-most commonly implicated medication in hospitalizations for adverse drug events (ADEs) in the elderly, comprising a quarter of all ADE hospitalizations along with oral hypoglycemic agents among this demographic.[12] In all, insulin-related hypoglycemia accounts for nearly 100,000 ED visits and 30,000 hospitalizations annually, resulting in >$600 million in costs over a 5-year period (2007–2011).[13] Furthermore, admission for dysglycemia (i.e., hyper- or hypoglycemia) is a strong predictor for a readmission within 30 days due to dysglycemia.[14,15] This impact is apparent regardless of severity, as both NSHE and SH predispose individuals to a higher risk of CV events, hospitalization, and all-cause mortality. SH in particular has a profound effect on mortality, with a 2.5-fold greater risk of death any time after an episode and a 4-fold higher risk 15 days after an episode.[16]

Patients with T1D report an average of up to 3 episodes of SH (i.e., those requiring the assistance of another person) per year.[17] Studies using CGM to evaluate the incidence hypoglycemia demonstrate much more frequent episodes of clinically important hypoglycemia (<54 mg/dL), ranging from 0.23 to 0.31 events per 24 hours.[18] These episodes have a profound impact on treatment decision making and adherence to prescribed therapy, potentially resulting in extended periods of hyperglycemia from an aversion to treatment. In the week following an NSHE, respondents required an average of 5.6 extra BG test strips and insulin users decreased their insulin dose by 25%.[19,20] In addition to the fear of hypoglycemia being a key contributing factor to the fact that 70% of patients do not use insulin as prescribed, the episodes themselves can have an impact on daily life and productivity/indirect costs.[19,20] Of 1400 responders with NSHEs, 22.7% were late for work or missed a full day. Productivity loss was highest for NSHEs occurring during sleep, with an average of 14.7 working hours lost.[20] Therefore the adverse effects of hypoglycemia beg the attention of payer stakeholders, as well as their employer purchasers.

The Evolution of Diabetes Technology and Glycemic Targets

The prominence of stringent glycemic control in clinical guidelines and published literature, juxtaposed with the risk of hypoglycemia, highlights the importance of a more sophisticated approach to diabetes management. The introduction of blood glucose test strips, glucose meters, and the potential for self-monitoring of blood glucose (SMBG) in the 1960s, 1970s, and 1980s represented the initial step toward widening the breadth of assessment and data collection in individual diabetes management.[5] CGM eventually followed and further revolutionized precision care, culminating in real-time CGM (rtCGM) systems that offer an abundance of data in a 24-hour period, independent of patient behavior.[5] Insulin pumps evolved similarly, ultimately being incorporated with CGM in integrated systems for select patient populations.

CURRENT GAPS IN DIABETES MANAGEMENT AND CLINICAL PRACTICE (CONTINUED)

The Evolution of Diabetes Technology and Glycemic Targets (continued)

With these advancements in diabetes health technology, leading clinicians and professional organizations have begun to re-evaluate existing outcomes measures and standards of care. Although A1C—once the preeminent surrogate marker for the development of long-term diabetes complications in patients with T1D and T2D—reflects average glucose over a 2- to 3-month period, its limitation is the lack of information about acute glycemic excursions and the acute complications of hyper- and hypoglycemia.[21] Furthermore, A1C also fails to identify the magnitude and frequency of intra- and interday glucose variation, and measurement may be confounded by certain conditions such as anemia, hemoglobinopathies, iron deficiency, and pregnancy.[21] Even in the absence of such clinical scenarios, the A1C test can fail at times to accurately reflect mean glucose.[21]

While A1C remains an important measure in clinical decision making, the advent of CGM has allowed for more inclusive targets in clinical practice and a more comprehensive perspective of glycemic control. Furthermore, the effective use of CGM data to optimize clinical outcomes requires the user to interpret the collected data and act upon them appropriately via common metrics for assessment of CGM glycemic status, graphical visualization of the glucose data and CGM daily profile, and clear clinical targets. To this end, a Steering Committee was formed in 2017 to identify and define clinically meaningful T1D outcomes beyond A1C with a focus on hypoglycemia, hyperglycemia, and time in range (TIR) among others.[22] Representatives from the American Association of Clinical Endocrinologists (AACE), the American Association of Diabetes Educators (AADE), ADA, the Endocrine Society, Juvenile Diabetes Research Foundation (JDRF) International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange comprised the committee, which outlined specific clinical criteria for the aforementioned measures:[22]

- TIR
  - % of time in “safe” range (70-180 mg/dL)
- Hypoglycemia (Level 1)
  - % of time spent <70 mg/dL
- Hypoglycemia (Level 2)
  - % of time spent <54 mg/dL
- Hyperglycemia (Level 1)
  - % time spent >180 mg/dL
- Hyperglycemia (Level 2)
  - % time spent >250 mg/dL

CURRENT GAPS IN DIABETES MANAGEMENT AND CLINICAL PRACTICE (CONTINUED)

The Evolution of Diabetes Technology and Glycemic Targets (continued)

Building upon these criteria, in February 2019, the Advanced Technologies & Treatments for Diabetes (ATTD) Congress assembled an international panel of individuals with diabetes and clinicians and researchers with expertise in CGM.[21] The objective was to develop clinical CGM-based targets to supplement the currently agreed-upon metrics for CGM-derived times in glucose ranges (within target range, below target range, above target range) in order to provide guidance for clinicians, researchers, and individuals with diabetes in using, interpreting, and reporting CGM data in routine clinical care and research **(Figure 1)**.[21] Later in 2019, the ADA adopted congruent targets in their Standards of Medical Care in Diabetes to reflect a more comprehensive perspective specific to the use of CGM in clinical practice.[24] Just as evidence supporting tight glycemic control measured via A1C was shown to reduce microvascular complications, the TIR measure is continually supported by a growing body of robust evidence demonstrating its role as a surrogate marker for reducing the cumulative incidence of complications such as MI, end-stage renal disease (ESRD), severe vision loss, and amputation in both T1D and T2D.[25]

"Knowledge of CGM technology and differentiation between devices is lacking. There's a lack of knowledge of the outcomes data. Time in range is a huge metric but many payers may be naïve to this; same with purchasers. We aren't entirely familiar with this stuff."

– Payer Representative

Over the past several years, CGM has gained traction in clinical practice as the standard of care for all patients treated with intensive insulin therapy (IIT). It has been endorsed in this role by numerous clinical societies and government organizations, including the ADA, AACE, Endocrine Society, ATTD, AADE, International Society for Pediatric and Adolescent Diabetes (ISPAD), US Food and Drug Administration, and Centers for Medicare and Medicaid Services (CMS). However, with a myriad of technologies, devices, and systems available, it is important to differentiate between these options and their capabilities. To achieve truly comprehensive knowledge of a patient's magnitude and frequency of intra- and inter-day glucose variation, a multitude of ongoing measurements must be captured and recorded, representing an unattainable goal for traditional SMBG interventions **(Figure 2)**. While rtCGM is capable of this level of intensive measurement, intermittently scanned CGM (isCGM) needs to be actively used by the patient in order to be effective.[22] To further elucidate these and other technical nuances in therapeutic CGM that affect clinical utility, a detailed assessment of the category and the evidence supporting its use is warranted.

THERAPEUTIC CGM AND ITS ROLE IN PRECISION DIABETES MANAGEMENT

SMBG has long represented a key component of effective diabetes management but features inherent limitations that can impact its utility, particularly in insulin-treated individuals with T1D and T2D. Requisite fingersticks to obtain blood samples can have a negative influence on patient adherence and are beleaguered by inconvenience in work or school settings. Furthermore, this modality is susceptible to user error due to poor testing technique, inadequate blood sample, presence of contaminating substances on fingers, and other factors that may lead to inaccuracy.[26] The clinical utility of SMBG is also severely limited due to the measurement of glucose at a single "point in time" and without provision of indicators of changing glucose. This absence of alerts for impending hypo- or hyperglycemia may result in inappropriate therapy decisions. In addition, reliance on patients' decisions and abilities to measure glucose at a given time limits the use of SMBG during the night, resulting in nocturnal and asymptomatic hypoglycemia often going undetected.

"The combination of the numbers and the trend arrows with rtCGM really shows patients what they need to do; it gives them confidence in self-treatment."

– Provider Representative

Differentiating Available CGM Classes

The emergence of CGM as a new standard of care has addressed many of the underlying limitations of SMBG by providing continuous measurement at 1- to 5-minute increments of glucose concentrations in the interstitial fluid, which correlate with blood glucose levels.[27] This provides information about immediate glucose levels, allowing analysis of CGM data by either the user or clinician to provide a more complete picture of glycemic patterns. As such, CGM can offer insights into the duration, frequency, and causes of fluctuations in blood glucose levels to help identify and prevent deleterious periods of hypoglycemia and hyperglycemia, thereby improving the overall quality of care over SMBG.[23] However, two types of CGM systems are now available–rtCGM and isCGM–and the extent to which they close the gaps inherent in traditional SMBG modalities serve as differentiating characteristics. rtCGM systems automatically transmit a continuous stream of glucose data to the user in real time, provide alerts and active alarms, and transmit glucose data (trend and numerical) to a receiver, smart watch, or smartphone. Comparatively, the current isCGM system collects the same type of glucose-related data, but requires the user to purposely scan the sensor to obtain information and does not feature active alerts and alarms **(Table 1).**[24,28,29,30,31,32,33,34]

THERAPEUTIC CGM AND ITS ROLE IN PRECISION DIABETES MANAGEMENT (CONTINUED)

Differentiating Available CGM Classes (continued)

In addition to the fundamental attributes differentiating available CGM modalities, these systems can be characterized by differences in calibration, accuracy, and interoperability. As a result of these differences, specific criteria have been outlined to guide the selection of either rtCGM or isCGM among different patient types.[23] According to these patient selection criteria, rtCGM is best suited to patients with an increased risk for hypoglycemia, including physically active patients, those with IAH, frequent hypoglycemia or severe hypoglycemia, and/or significant glycemic variability. Similarly, those who experience hypoglycemic fear and patients who may benefit from data sharing (e.g., pediatric patients, elderly, people who travel alone) represent ideal candidates for rtCGM.[23] In addition, patients with high A1C, those trying to increase TIR (70–180 mg/dL), or those who desire tighter glycemic control are also likely to benefit from rtCGM. Furthermore, rtCGM is well suited to patients who want to use an insulin pump that adjusts basal insulin delivery and delivers automatic correction boluses.[27] Conversely, isCGM represents a satisfactory intervention for patients with prediabetes, those on oral agents only, or those only on basal insulin requiring titration.[23] In addition, patients with a limited risk for hypoglycemia and those who do not have any degree of hypoglycemia unawareness represent candidates for isCGM, as do patients with T2D who are not willing or able to perform SMBG as often as needed for clinical decision making. Similarly, isCGM is well suited for patients who meet the aforementioned criteria in addition to having difficulty taking fingersticks because of manual dexterity issues. Generally speaking, patients prescribed isCGM should not require glycemic-based alerts and alarms and should be willing to scan their device several times a day.[23]

In terms of interoperability, the Dexcom G6 became the first system to be classified as integrated CGM (iCGM) by the FDA in 2018.[33] This indicates that the G6 is licensed to be used as part of an integrated system with other compatible medical devices and electronic interfaces, which may include automated insulin dosing systems, insulin pumps, blood glucose meters, or other electronic devices used for diabetes management.[33] Although integrated CGM/pump systems are not a novel concept, the iCGM classification is based on cross-platform interoperability and special controls enabled by the FDA allows developers of future iCGM systems to bring their products to market in the least burdensome manner possible.[33]

"rtCGM is a safety-enhancing intervention; isCGM is not functional in this capacity."

– Provider Representative

THERAPEUTIC CGM AND ITS ROLE IN PRECISION DIABETES MANAGEMENT (CONTINUED)

Characterizing the Clinical Value of CGM

Moving from technical attributes to clinical outcomes, CGM in general has seen increased uptake in recent years, with improvements in A1C across multiple demographics. In the T1D Exchange registry involving >25,000 patients, CGM use increased from 7% in 2010–2012 to 30% in 2016–2018, rising >10-fold in children aged <12 years old. Furthermore, HbA1c levels were lower in CGM users than nonusers irrespective of age or insulin delivery method **(Figure 3)**.[35] Additional data from the registry showed clear associations between increased adoption of CGM and decreased incidence of both severe hypoglycemia and diabetic ketoacidosis.[35]

rtCGM specifically has shown remarkable potential for improvement in several key measures of quality care in the management of diabetes. From a population perspective, rtCGM in real-world practice demonstrates reductions in hyperglycemia and hypoglycemia while improving TIR.[36] In addition to these and other associated clinical outcomes, a number of studies subsequently discussed also show improvements in humanistic outcomes associated with rtCGM, such as quality of life (QoL) measures, hypoglycemic fear, and treatment confidence. In addition to empowering patients, the data collected via rtCGM can be shared with clinicians; this offers a more comprehensive understanding of the patients' individual lifestyle, treatment, and response trends and thereby has the potential to increase the accuracy of health care interventions.

"rtCGM modifies behavior and gets more patients to goal."

– Provider Representative

The COMISAIR study—the longest running real-world rtCGM study performed to date—assessed the clinical impact of four treatment strategies in adults with T1D: real-time continuous glucose monitoring (rtCGM) with multiple daily insulin injections (rtCGM+MDI), rtCGM with continuous subcutaneous insulin infusion (rtCGM+CSII), self-monitoring of blood glucose with MDI (SMBG+MDI), and SMBG with CSII (SMBG+CSII).[37] In this 3-year, nonrandomized, prospective, clinical trial following 94 participants with T1D, the main end points were changes in A1C, TIR (70–180 mg/dL [3.9–10 mmol/L]), time below range (<70 mg/dL [<3.9 mmol/L]), glycemic variability, and incidence of hypoglycemia. At 3 years, the rtCGM groups (rtCGM+MDI and rtCGM+CSII) had significantly lower A1C (7.0% [53 mmol/mol], P=0.0002, and 6.9% [52 mmol/mol], P<0.0001, respectively), compared with the SMBG+CSII and SMBG+MDI groups (7.7% [61 mmol/mol], P=0.3574, and 8.0% [64 mmol/mol], P=1.000, respectively), with no significant difference between the rtCGM groups **(Figure 4)**. Significant improvements in percentage of TIR were observed in the rtCGM subgroups (rtCGM+MDI, 48.7–69.0%, P<0.0001; and rtCGM+CSII, 50.9–72.3%, P<0.0001) and in the SMBG+CSII group (50.6–57.8%, P=0.0114). Significant reductions in time below range were found only in the rtCGM subgroups (rtCGM+MDI, 9.4–5.5%, P=0.0387; and rtCGM+CSII, 9.0–5.3%, P=0.0235).

THERAPEUTIC CGM AND ITS ROLE IN PRECISION DIABETES MANAGEMENT (CONTINUED)

Characterizing the Clinical Value of CGM (continued)

Taking a closer look at the effect of rtCGM use on hypoglycemic events, HypoDE was a 6-month, multicenter, open-label, parallel, randomized controlled trial evaluating episodes of hypoglycemia (≤54 mg/dL for ≥20 min) among 149 adult participants at high-risk for severe hypoglycemia assigned to either rtCGM or SMBG as control.[38] The mean number of hypoglycemic events per 28 days among participants in the rtCGM group was reduced from 10.8 to 3.5, while reductions among control participants were negligible (from 14.4 to 13.7). Ultimately, the incidence of hypoglycemic events decreased by 72% for participants in the rtCGM group (incidence rate ratio 0.28 [95% CI 0.20–0.39], *P*<0.0001).

In the randomized GOLD clinical trial of 161 adults with type 1 diabetes, glycemic control was improved during rtCGM compared with conventional treatment (A1C of 7.92% vs. 8.35% [63 vs. 68 mmol/mol]).[39] Evaluations performed from the GOLD randomized trial reported that time with nocturnal hypoglycemia (glucose levels <70 mg/dL) was reduced by 48% (10.2 vs. 19.6 min each night, *P*< 0.001) and severe nocturnal hypoglycemia (glucose levels <54 mg/dL) was reduced by 65%. (3.1 vs. 8.9 min, *P*< 0.001). For the corresponding glucose cutoffs, daytime hypoglycemia was reduced by 40% (29 vs. 49 min, *P*<0.001) and 54% (8 vs. 18 min., *P*<0.001), respectively.[40] Compared with SMBG, rtCGM use also improved hypoglycemia-related confidence in social situations (*P*=0.016) and confidence in more broadly avoiding serious problems due to hypoglycemia (*P*=0.0020). Participants also reported greater confidence in detecting and responding to decreasing blood glucose levels (thereby avoiding hypoglycemia) during CGM use (*P*=0.0033) and indicated greater conviction that they could more freely live their lives despite the risk of hypoglycemia (*P*=0.022).

A total of 158 participants with poorly controlled T1D were assigned to either rtCGM or SMBG (control) in the randomized DIAMOND (Multiple Daily Injections and Continuous Glucose Monitoring in Diabetes) trial.[41] Mean HbA1c reduction from baseline was 1.1% at 12 weeks and 1.0% at 24 weeks in the CGM group and 0.5% and 0.4%, respectively, in the control group (repeated-measures model *P*<.001). At 24 weeks, the adjusted treatment-group difference in mean change in HbA1c level from baseline was -0.6% (95% CI, -0.8% to -0.3%; *P*<0.001). Median duration of hypoglycemia at less than <70 mg/dL was 43 min/d (IQR, 27-69) in the CGM group vs 80 min/d (IQR, 36-111) in the control group (*P*=0.002). At baseline and study end, participants completed QOL measures that assessed overall well-being (WHO-5), health status (EQ-5D-5L), diabetes distress (DDS), hypoglycemic fear (worry subscale of the HFS-II), and hypoglycemic confidence (HCS). At study end, CGM participants completed the CGM Satisfaction Survey.[42] Associations between CGM satisfaction and change in QoL outcomes and in glycemic control indices were assessed. The CGM group demonstrated a greater increase in hypoglycemic confidence (*P*=0.01) and a greater decrease in diabetes distress (*P*=0.01) than the SMBG group. CGM satisfaction was not significantly associated with glycemic changes but was associated with reductions in diabetes distress (*P*<0.001) and hypoglycemic fear (*P*=0.02) and increases in hypoglycemic confidence (*P*<0.001) and well-being (*P*=0.01).

THERAPEUTIC CGM AND ITS ROLE IN PRECISION DIABETES MANAGEMENT (CONTINUED)

Characterizing the Clinical Value of CGM (continued)

The use of rtCGM interventions has demonstrated clinical validity across all indicated age groups, but its value continues to be elucidated in specific demographics, particularly those at risk for IAH and hypoglycemia. Among these, elderly patients present a particular challenge, with over half of older T1D participants in the WISDM (Wireless Innovation for Seniors with Diabetes Mellitus) trial spending at least an hour a day with glucose levels <70 mg/dL at baseline.[43] In the trial, those with reduced hypoglycemia awareness also spent >2x as much time than those without reduced hypoglycemia awareness in a serious hypoglycemia range (glucose levels <54 mg/dL) at baseline.[43] A total of 203 participants aged >60 years across 22 sites were randomized (1:1) to either rtCGM or blood glucose monitoring (BGM) with masked CGM for 6 months.[44] The rtCGM group spent less time in hypoglycemia (<70 mg/dL) compared with the BGM group (39 min vs. 72 min; $P<0.001$) and 2 more hours per day in range (70–180 mg/dL). Furthermore, those on rtCGM reported significantly fewer severe hypoglycemic events (1 vs. 10). A1C reduction was also greater in the CGM group. These benefits were observed regardless of insulin pump use versus MDI.

In addition to these and a number of other studies demonstrating a clearly defined benefit associated with rtCGM pertaining to well-established outcomes measures, the body of evidence continues to grow in other disciplines. For example, in a bivariate analysis from a study on kidney disease in T1D from the T1D Exchange network, the use of CGM appeared to have a kidney-protective benefit.[45] In the study population, 47% of CGM users experienced an adverse renal outcome (defined as an estimated glomerular filtration rate <60 or albuminuria) compared with 56% of non-CGM users ($P=0.04$).

Despite this wealth of evidence supporting the value of CGM in clinical practice and increased utilization of CGM in recent years, the majority of patients with diabetes do not use the technology, representing an opportunity for improvement in the quality of care.[35] In a 2017 survey of 533 adults and 114 parents of children with T1D, 39.5% of respondents reported ''not covered by insurance'' as their primary reason for not adopting CGM technology.[46] A similar survey identified ''cost of supplies'' as the top reason for discontinuing CGM use.[47] These latter findings indicate that certain elements of benefit design may create a cost-prohibitive environment for patients even when CGM coverage exists. In light of unfavorable coverage and access parameters being identified as key barriers to uptake, the insights of payer and purchaser stakeholders, in conjunction with those of leading clinicians, were sought at the *Therapeutic CGM Health Care Stakeholder Summit*.

"The cost difference between rtCGM and isCGM is not large enough to make limited access [to rtCGM] justifiable."

– Provider Representative

ADVISORY BOARD FINDINGS

The *Therapeutic CGM Health Care Stakeholder Summit* convened on November 7, 2019, in Washington, DC. The purpose of the meeting was to gather input from stakeholder participants pertinent to the coverage and application of therapeutic CGM in managed care. This input was intended to advance the uptake and appropriate coverage of evidence-based health technology interventions by managed care organizations (MCOs) and various payers.

In attendance were key health care stakeholders representing the interests of both providers, payers, and employers:

BOARD MEMBER	AFFILIATION
PROVIDER REPRESENTATIVES	
Daniel DeSalvo, MD	Texas Children's Hospital
Janet McGill, MD	Washington University
Alyson E. Shirer, PharmD	South University School of Pharmacy
PAYER/EMPLOYER REPRESENTATIVES	
Edmund Pezalla, MD, MPH	Enlightenment Bioconsult, LLC; Former, Aetna, Inc.
Joseph Albright, PharmD	BCBS of North Carolina
Jeff Dunn, PharmD, MBA	Former, Magellan Rx
Vanita K. Pindolia, PharmD, BCPS, MBA	Henry Ford Health System and Health Alliance Plan
Jay Weaver, PharmD, MPH	HCSC
Gary Melis, RPh	Network Health
Troy Ross, MSM	Mid-American Health Care Coalition

Payer and Purchaser Considerations on CGM Access and Coverage

Advisors attending the *Therapeutic CGM Health Care Stakeholder Summit* were instrumental in helping to identify key areas in which payer perspectives and approaches may be misaligned with optimal outcomes in diabetes management. In 2017, the Centers for Medicare and Medicaid Services (CMS) made a milestone ruling, establishing coverage specifically for "therapeutic CGM": a designation applying only to those CGM systems approved for use in making treatment decisions without a fingerstick (i.e., "non-adjunctive use").[48] Today, nearly all commercial plans and many state Medicaid plans cover therapeutic CGM for patients with T1D or T2D using IIT who meet medical criteria. However, restrictive coverage criteria founded on a system that currently lags behind the emerging evidence and shifting disease management paradigm have resulted in suboptimal care. These current gaps are likewise influenced by policy and infrastructure that have yet to be updated due to internal and external influences.

ADVISORY BOARD FINDINGS (CONTINUED)

Payer and Purchaser Considerations on CGM Access and Coverage (continued)

TIR—a measure that is largely under-recognized by payers and one that represents a hallmark of CGM clinical successes—is being increasingly shown to significantly affect both clinical and economic outcomes. Although A1C remains an important surrogate marker in clinical trials and practice, it is perhaps even more firmly entrenched in payer policy, where National Committee for Quality Assurance (NCQA) measures and Medicare Star Ratings continue to drive the business of health care. Conversely, TIR may be overlooked by MCOs despite a recent emphasis in consensus recommendations. Of particular interest to payer professionals, economic models estimate a $2.8 billion incremental 10-year cost reduction from lowering the rate of hypoglycemic events in people with T1D as a result of improving TIR.[25] Additional economic modeling places the 10-year cost reduction of improving TIR from 58% to 70% or 80% in T1D and T2D patients at $4.2 to $7 billion **(Figure 5)**.[25] Findings demonstrating distinct reductions in health care resource utilization directly associated with rtCGM further support a renewed focus on facilitating access to health care technology. For example, instating reimbursement for rtCGM in one member population elicited an 81.8% reduction in hospitalizations for hypoglycemia or diabetic ketoacidosis and a 40.6% reduction in work absenteeism.[36] The presumed kidney-protective benefit of CGM may also garner the attention of payers and purchasers, with ESRD being a key driver of catastrophic claims and 44% of cases attributed to diabetes.[49] Benefit design and coverage policy should be aligned with these findings and the growing body of evidence to impact clinical and economic outcomes for diabetes in a meaningful way.

> *"ESRD is a top-10 stop loss claim condition. If you can avert some of these cases, you've got the attention of employers."*
>
> – Employer Representative

Facilitating CGM Coverage and Access

To this end, timely, unencumbered access to therapeutic CGM for appropriate patients is in the best interest of all health care stakeholders. Reinforcing this notion, an analysis investigating the efficacy and safety of rtCGM initiation within 1 year of T1D among 336 children, adolescents, and adults showed that—regardless of insulin delivery system—early initiation of CGM within 1 year from T1D diagnosis was associated with better glucose control and fewer diabetes-related emergency visits.[50] Specifically, after 2.5 years of follow-up, the MDI+CGM group had 1.5% ± 0.2% lower A1C than the MDI only group (7.7% ± 0.2% vs. 9.2% ± 0.04%, $P<0.0001$), and the CSII+CGM group had 0.7% ± 0.1% lower A1C than the CSII only group (8.0% ± 0.08% vs. 8.7% ± 0.07%, $P<0.0001$). The MDI+CGM group had significantly lower A1C than the CSII only group (7.7% ± 0.2% vs. 8.7% ± 0.07%, $P<0.0001$) **(Figure 6a)**. The proportion of CGM users who visited the emergency department for severe hypoglycemia or hyperglycemia was significantly lower than that of non-CGM users ($P=0.003$), highlighting the potential impact of CGM on health care resource utilization **(Figure 6b)**.

ADVISORY BOARD FINDINGS (CONTINUED)

Barriers to CGM Access: Utilization Management and Benefit Design

Despite this and other compelling evidence, payer benefit design and utilization management interventions are not fully aligned with the adoption of timely and convenient access to CGM, particularly via traditional coverage arrangements under the medical benefit as durable medical equipment (DME). Specifically, prior authorization (PA) criteria based on diabetes type and history of SMBG use represent an unnecessary barrier, ignoring the burden that frequent SMBG places on members.[51] Furthermore, no evidence exists showing that frequent SMBG or type of diabetes is predictive of successful outcomes with CGM use.[51] Beyond specific PA criteria, the PA process itself creates a tremendous burden for prescribers and patients, extending the potential timeframe from prescription to receipt of the CGM device from mere hours to multiple weeks. US physicians encounter an average of 31 PAs per week, accounting for an average of 14.9 hours of processing time at an average cost of $83,000 per prescriber annually.[52,53] Considering the current number of practicing physicians in the United States, these interactions with payers cost providers approximately $83.4 billion annually.[54] In terms of patient impact, 91% of US physicians report care delays as a result of PAs, with 75% reporting prescription abandonment and 91% reporting a negative effect on treatment outcomes.[48]

"Some plans still require three hypoglycemic events prior to covering CGM. If you have just one hypoglycemic event and go to the ED, you've already paid for a CGM device."

– Employer Representative

The Advantages of Pharmacy Benefit Coverage

Alternatively, a more contemporary approach to the coverage of CGM is under the pharmacy benefit. The origins of this trend in benefit design lie in the coverage of glucose test strips, which were moved from the medical benefit to the pharmacy benefit by the vast majority of payers several years ago due to rebates from manufacturers and simplified access for members at community pharmacies. Coverage under the pharmacy benefit allows for real-time adjudication and automated utilization management via step edits instead of PA, reducing the administrative burden on payers and providers alike. At the same time, this approach enhances access for the member by allowing for a more rapid and seamless receipt of the device, often taking only a matter of hours or a couple days as opposed to weeks under the medical benefit/DME. Pharmacy coverage of CGM devices and supplies also allows patients to easily access these products at local community pharmacies and provides for potentially lower out-of-pocket (OOP) cost to the member, which is an especially important consideration for low-resource patients. Access at community pharmacies also integrates the pharmacist as an allied health care provider and increases member contacts, potentially improving patient education, therapeutic adherence, and clinical outcomes. In keeping with these trends, retail pharmacy chains are also streamlining Medicare Part B pharmacy access for CGM interventions.

ADVISORY BOARD FINDINGS (CONTINUED)

"Access under the DME takes weeks, pharmacy takes moments."

– Payer Representative

Blueprint for Moving rtCGM Coverage from the Medical Benefit to the Pharmacy Benefit

An advisor in attendance at the *Therapeutic CGM Health Care Stakeholder Summit* from a large regional payer shared his plan's experience moving rtCGM coverage from the medical benefit to the pharmacy benefit. The subsequent approach serves as a blueprint for assessing cost and utilization under both benefits and implementing the appropriate policy changes to achieve appropriate utilization of rtCGM with pharmacy coverage.

The plan's Pharmacy Services department received demonstration devices from the rtCGM manufacturer to initiate the process after a review of consensus guidelines and the realization that CGM was underutilized among plan member that stood to benefit the most from it: those on IIT delivered via pump or MDI. A member of the department's leadership wore the device and shared results with several others via the connectivity option to assess ease-of-use and perceived accuracy/utility. These plan stakeholders were able to experience the device's alerts for postprandial glycemic excursions and consider how this information may empower members with T1D and insulin-treated T2D, allowing them to make informed treatment decisions. Having found the rtCGM system to be insightful and user-friendly, the evaluation of potential cost and utilization under the pharmacy benefit ensued.

Billing codes were then pulled for CGM under the medical benefit. Using these codes in a retrospective analysis of claims data, Pharmacy Services was able to determine the current frequency of rtCGM utilization within the plan and calculate the total cost under the medical benefit using the fee schedule. This calculated cost was used as a comparator for the new estimated cost under the pharmacy benefit. Projected cost under the pharmacy benefit was estimated by contacting the plan's pharmacy benefits manager (PBM) to determine the contracted rates based on wholesale acquisition cost (WAC) and accounting for manufacturer rebates. In performing this estimation, it was presumed that utilization of rtCGM would increase noticeably under the pharmacy benefit due to automated utilization management and enhanced access for the member. Finding the cost to be lower for the plan under the pharmacy benefit, leadership proceeded with an evaluation of current medical benefit policy.

ADVISORY BOARD FINDINGS (CONTINUED)

"You're leaving money on the table in the medical benefit. Look at your medical claims. You're already paying for it, but with rebates, improved access, and better outcomes, pharmacy is the way to go."

– Payer Representative

Blueprint for Moving rtCGM Coverage from the Medical Benefit to the Pharmacy Benefit (continued)

The Pharmacy Services department consulted with the Medical Policy and Benefits departments to determine precisely how rtCGM utilization was being managed under the medical benefit. After reviewing prior authorization criteria, the plan's pharmacy stakeholders looked for any stipulations in the medical policy that precluded CGM from being moved to the pharmacy benefit. Finding the benefit language to be flexible, payer pharmacy leadership investigated precisely how the plan's documents were filed with the state Department of Insurance to determine whether or not they would require a resubmission for coverage under the pharmacy benefit. After addressing the specificities of insurance policy, the Pharmacy Services department moved on to addressing utilization management under the pharmacy benefit.

Plan pharmacy leadership opted to employ a smart edit under the pharmacy benefit for utilization management. Such an approach leverages the opportunity for simplified utilization management and administrative efficiencies inherent to the pharmacy benefit. The specific edit featured an automated look back in the claims data for a previous insulin prescription as the criterion for approval of rtCGM coverage. In addition, quantity limits were instated for CGM supplies prior to launching coverage under the pharmacy benefit.

"A step edit looking back for insulin creates an opportunity for savings because you're letting the benefit do the work en route to approving CGM rather than adding administrative burden."

– Payer Representative

ADVISORY BOARD FINDINGS (CONTINUED)

Blueprint for Moving rtCGM Coverage from the Medical Benefit to the Pharmacy Benefit (continued)

With the benefit design change now in place, the plan is tracking the utilization of rtCGM by members as part of an ongoing process. Ultimately, the guideline-endorsed qualifications of rtCGM in T1D and insulin-treated T2D served as the impetus for this change, along with the ability for the plan to offer 4 times more members access to this technology under the pharmacy benefit at a similar overall cost to the current pricing under the medical benefit. Favorable reviews upon first-hand product demonstrations and the determination that pharmacy benefit coverage would almost invariably result in cost savings for the plan further supported the decision. Although the change in benefit design resulted in added spend to the pharmacy budget, it ultimately saved the plan money in total costs—a trend that may be potentiated over time. The first quarter saw the anticipated influx of pharmacy utilization before access to rtCGM on the medical benefit was closed, with the cost per member being substantially lower on the pharmacy benefit. Furthermore, among 1,100 members, total costs were 15% lower during the 6 months following rtCGM initiation compared with the 6 months prior to rtCGM initiation; this trend was presumably driven by lower costs under the medical benefit, including lower ED utilization.

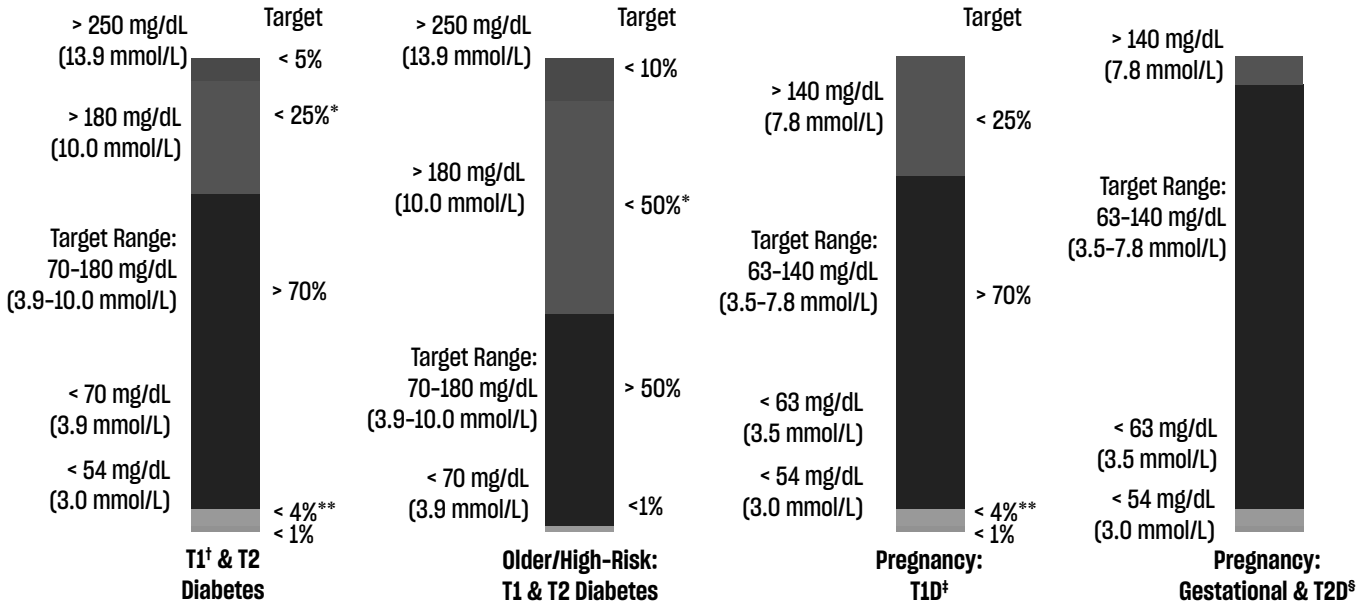
DISCUSSION

A century of advancement in the management of diabetes has the medical community on the precipice of a new era of precision management. The evolution of patient engagement and care from SMBG to rtCGM represents a crucial part of this narrative, finally illuminating the egregious diurnal and nocturnal glycemic variability inherent to patients with T1D and insulin-treated T2D. Accompanying these technical advances is a renewed perception of clinical targets and comprehensive outcomes measures, poised to transform diabetes management strategies.

The clinical utility and health care value of therapeutic CGM has been thoroughly established in the published literature. However, despite being cemented in consensus recommendations, uptake and utilization remain inadequate for truly "moving the needle" of care quality in a disease state that has seen such improvement yet is characterized by such unrealized potential. Health care payers and their employer purchasers represent a key piece to this puzzle, with restrictive coverage still hindering access to high-value health technology. Continued efforts to expand access to rtCGM data are crucial, along with steps to improve real-world data coordination and long-term outcomes improvement.

Moving forward, the medical community must continue to advocate for the assessment of an inclusive array of outcomes measures, realizing the heterogeneity of diabetes itself and the necessity of a sophisticated and personalized approach to management. At the same time, payers and employers should carefully evaluate the overarching distribution of health care dollars with the knowledge that improved access to rtCGM for appropriate patients offers immediate and long-term gains in terms of both improved outcomes and cost savings. Considering the rapid pace of developments in the field of diabetes management, the next advancement is likely right around the corner; however, CGM is positioned to play a critical role in quality care well into the unforeseen future.

FIGURE 1. CGM-BASED TARGETS FOR DIFFERENT PATIENT POPULATIONS.[21]



† For age <25., if the A1C goal is 7.5%, then set TIR target to approximately 60%.
‡ Percentages of time in ranges are based on limited evidence. More research is needed.
§ Percentages of time in ranges have not been included because there is very limited evidence in this area. More research is needed.
* Includes percentage of values >250 mg/dL (13.9 mmol/L).
** Includes percentage of values <54 mg/dL (3.0 mmol/L)

FIGURE 2. EXAMPLE OF REAL-WORLD GLYCEMIC VARIABILITY NOT CAPTURED BY SMBG DURING A 24-HOUR PERIOD

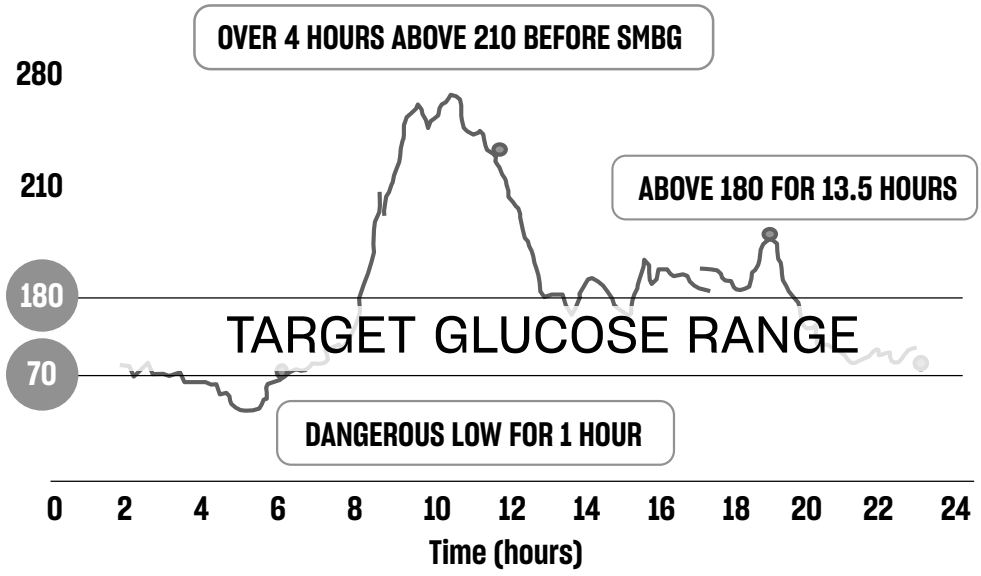


FIGURE 3. AVERAGE A1C LEVEL ACROSS CGM USERS AND NONUSERS STRATIFIED BY INSULIN DELIVERY METHOD IN THE T1D EXCHANGE REGISTRY[35]

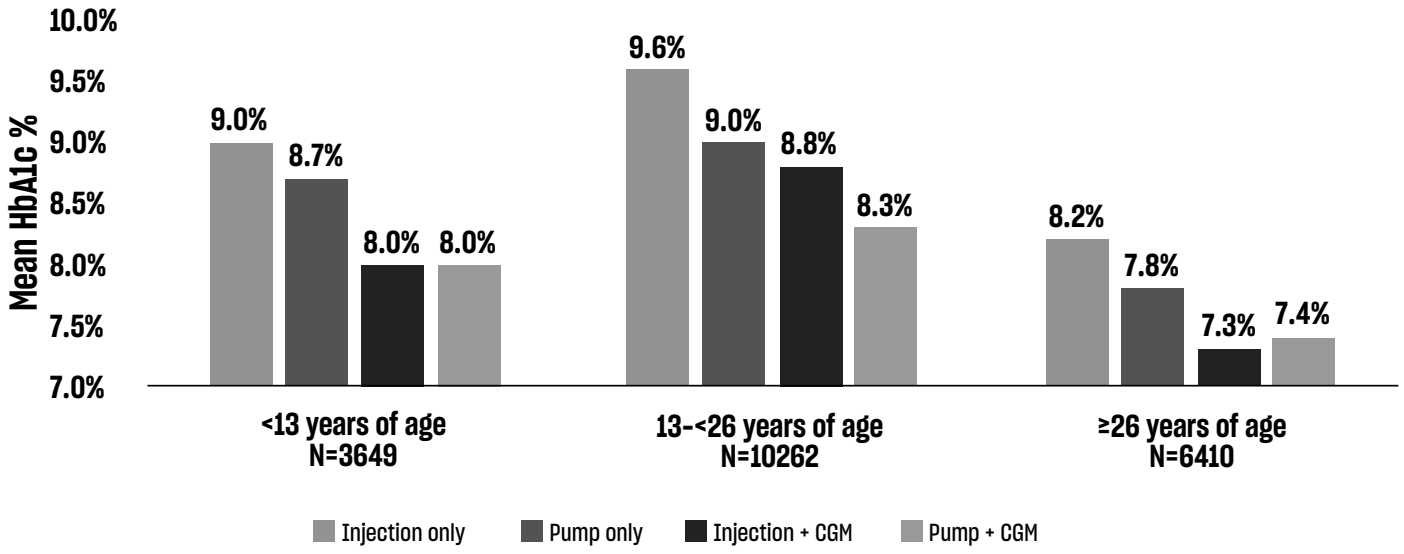


FIGURE 4. A1C OVER 3 YEARS OF FOLLOW-UP IN THE COMISAIR TRIAL OF RTCGM PLUS MDI OR INSULIN PUMP VERSUS SMBG PLUS MDI OR INSULIN PUMP.[37]

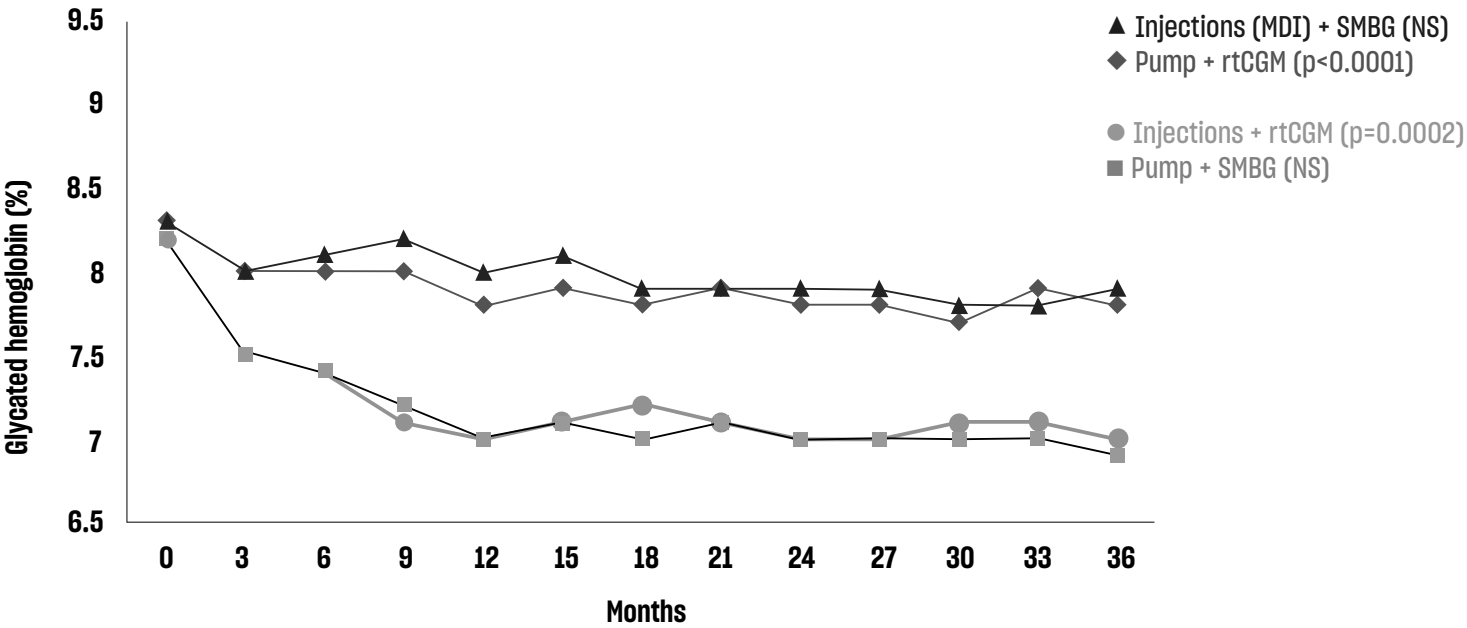


FIGURE 5. 10-YEAR COST REDUCTION BY IMPROVING TIR IN PEOPLE WITH T1 AND T2 DIABETES TO 70% AND 80% TIR (US$BN).[25]

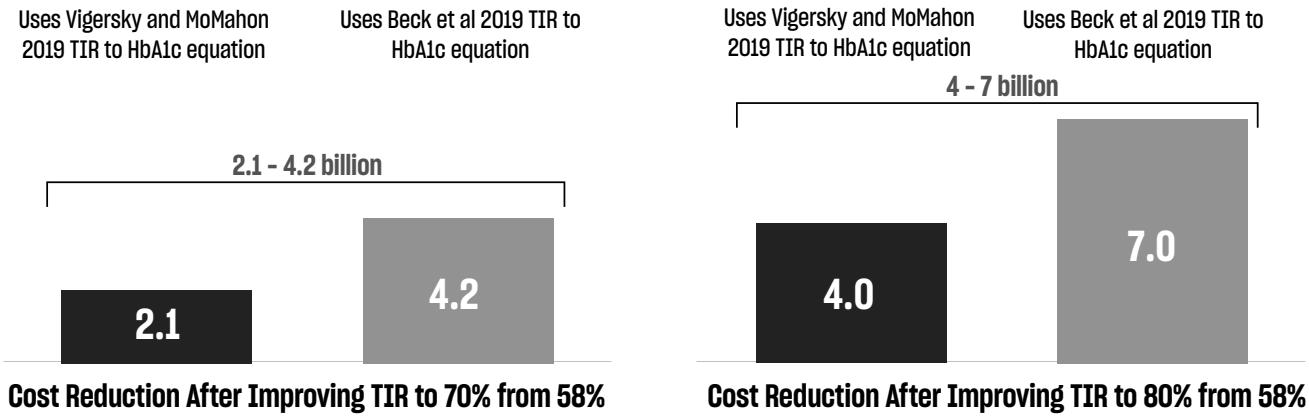


FIGURE 6. A.) A1C OVER 2.5 YEARS AFTER INITIATION OF CGM PLUS MDI OR CSII VERSUS SMBG PLUS MDI OR CSII WITHIN 1 YEAR OF DIAGNOSIS; B.) PROPORTION OF CGM VS NON-CGM USERS WHO HAVE REQUIRED AN ED VISIT OVER 2.5 YEARS.[50]

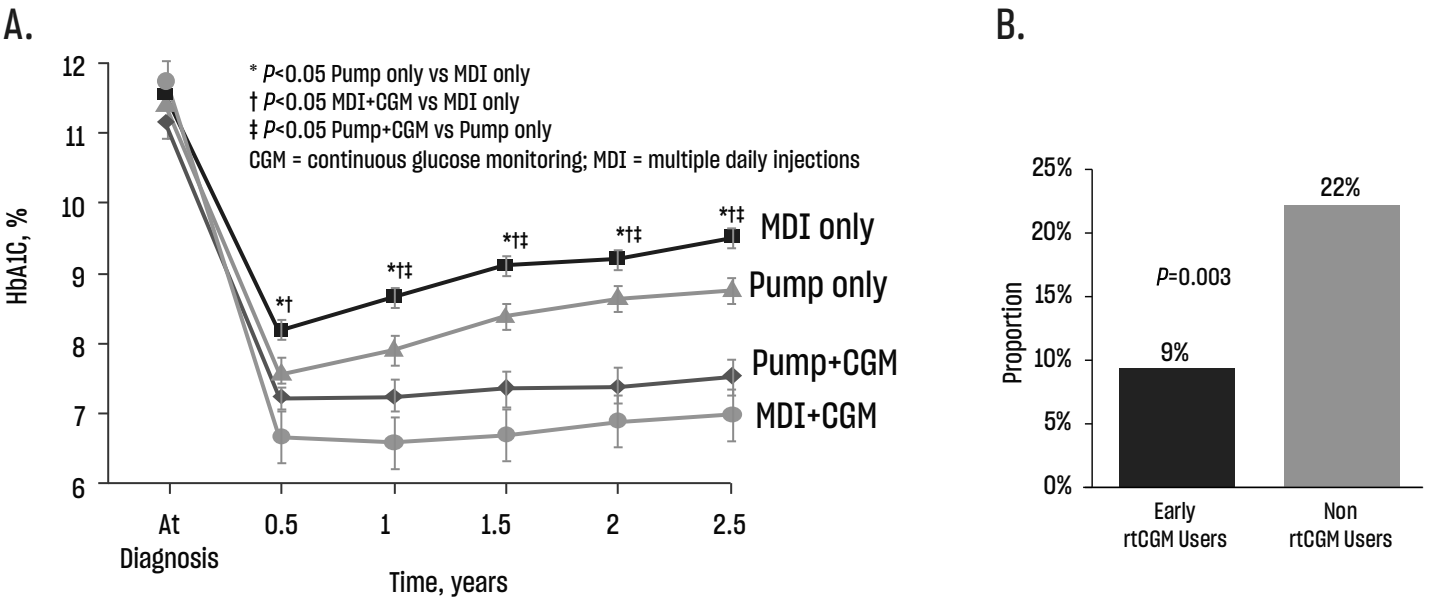


TABLE 1. COMPARISON OF ATTRIBUTES AND PERFORMANCE OF SELF-INSERTED THERAPEUTIC CGM SYSTEMS.[24,26-33]

PRODUCT ATTRIBUTES AND PERFORMANCE	G6® CGM SYSTEM (DEXCOM)[28]	FREESTYLE® LIBRE FLASH GLUCOSE MONITORING SYSTEM (ABBOTT)[29]
CGM Classification	Real-Time CGM	Intermittent Scan CGM
Continuous data availability	Data available **without** user intervention	Data available only **with** user intervention (i.e. user must scan sensor)
Age indication (years)	2+	18+
Confirmatory fingerstick required per labeled indications:		
- When experiencing symptoms that do not match sensor glucose readings	Yes	Yes
- When experiencing symptoms that may be due to low or high blood glucose	No	Yes
- During times of rapidly changing glucose (i.e., trend arrows ↑ ↓)	No	Yes
- To confirm hypoglycemia or impending hypoglycemia as reported by the sensor	No	Yes
- Anytime the check BG icon appears	No	Yes
- During first 12 hours of sensor wear	No	Yes
Meets integrated CGM Class Criteria	Yes	No
FDA Classification/Pathway Relative Risk Designation	Class II DeNovo33 Medium Risk	Class III PMA34 High Risk
Meets Medicare therapeutic CGM criteria	Yes	Yes
Factory-calibrated	Yes (manual calibration optional)	Yes
Ease of use/sensor insertion	No assembly required; 4 steps	No assembly required; 3 steps
Sensor wear	10 days	14 days
Sensor life, adults >18 (% sensors working at end of maximum indicated use)	94% @ 10 days	71.6% @ 14 days
Sensor warm-up time	2 h	1 h
FDA-approved sensor sites	Abdomen (adults) Abdomen, upper buttocks (pediatrics)	Upper arm

TABLE 1. COMPARISON OF ATTRIBUTES AND PERFORMANCE OF SELF-INSERTED THERAPEUTIC CGM SYSTEMS.[24,26-33] (CONTINUED)

PRODUCT ATTRIBUTES AND PERFORMANCE	G6® CGM SYSTEM (DEXCOM)[28]	FREESTYLE® LIBRE FLASH GLUCOSE MONITORING SYSTEM (ABBOTT)[29]
Protective Safeguards (alerts/alarms):		
Predictive hypoglycemia alert	Yes	No
- Provides updates without user interaction (i.e. during sleep)	Yes	No
- Real-time, customizable glucose alerts (low/high)	Yes	No
- Rapidly rising/falling rate of change alerts	Yes	No
- Urgent low glucose safety alarm	Yes	No
Moisture protection	Water resistant up to 8 feet for 24 h	Water resistant up to 3 feet for 30 min
Insulin pump integration	Yes; Tandem t:slim X2™	Yes; not commercially available
Smart insulin pen integration	Yes; Companion InPen™	Yes; not commercially available
Communication range	20 feet	1.5 in
Mobile device connectivity	Yes; iOS and Android via Bluetooth	Yes; iOS and Android can be used to scan sensor for data via near field communication
Remote monitoring	Yes; continuous	Yes; upon scanning
Known interfering substances	Hydroxyurea	Ascorbic Acid at doses >500 mg may cause falsely higher readings; Salicylic Acid at doses >650 mg may cause falsely lower glucose values[32]
FDA Warning for Use in Hypoglycemia Unawareness Patients	No	Yes
Data storage	Data automatically stored without user intervention	Data stored when user scans the sensor. Sensor must be scanned at least once every 8 hours to prevent data loss
EHR Integration Capability	Yes – Epic, Cerner (limited availability)	N/A
Overall accuracy MARD (average % discrepancy between CGM and reference YSI, 40-400 mg/dL)	9.0% (overall)	10.1% (SSED data)
	9.8% (adults)	
	7.7% (children)	
Hypoglycemia accuracy (Concurrence of sensor readings with YSI-measured values in the critically low range 40-60 mg/dL)	63%	25%
Accuracy during rapid rates of change (Concurrence of sensor readings with YSI- measured rates of change)		
Rapidly Falling: ≥ 2 mg/dL/min	53.3%	37.7%
Rapidly Rising: ≥ 2 mg/dL/min	71.3%	40.4%

TABLE 1. COMPARISON OF ATTRIBUTES AND PERFORMANCE OF SELF-INSERTED THERAPEUTIC CGM SYSTEMS.[24,26-33] (CONTINUED)

PRODUCT ATTRIBUTES AND PERFORMANCE	G6® CGM SYSTEM (DEXCOM)[28]	FREESTYLE® LIBRE FLASH GLUCOSE MONITORING SYSTEM (ABBOTT)[29]
ADA Standards of Care Recommendations & Level of Clinical Evidence[24] A = Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered B = Supportive evidence from well-conducted cohort studies C = Supportive evidence from poorly controlled or uncontrolled studies	When used properly, **real-time CGM** in conjunction with insulin therapy are a useful tool to lower A1C levels and/or reduce hypoglycemia in adults with type 1 diabetes who are not meeting glycemic targets, have hypoglycemia unawareness, and/or have episodes of hypoglycemia. **(A)** When used properly, **real-time CGM** devices in conjunction with insulin therapy are useful tools to lower A1c and/or reduce hypoglycemia in adults with T2D who are not meeting glycemic targets. **(B)** **Real-time CGM** may be used effectively to improve A1C levels, time in range, and neonatal outcomes in pregnant women with type 1 diabetes. **(B)** **Real-time CGM** should be used as close to daily as possible for maximal benefit. **(A)**	When used properly, **intermittently scanned CGM** in conjunction with insulin therapy are a useful tool to lowerA1C levels and/or reduce hypoglycemia in adults with type 1 diabetes who are not meeting glycemic targets, have hypoglycemia unawareness, and/or have episodes of hypoglycemia. **(C)** When used properly, **intermittently scanned CGM** devices in conjunction with insulin therapy are useful tools to lower A1C and/or reduce hypoglycemia in adults with T2D who are not meeting glycemic targets. **(B)** **Intermittently scanned CGM** should be scanned frequently, at a minimum once every 8 h. **(A)**

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