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Product Monograph

Continuous Glucose Monitoring With Dexcom G6

Dexcom G6®

Burden of Diabetes

Diabetes is a complex, chronic illness affecting more than 30 million Americans, or 9.4% of the population.[1] In 2017, the total cost of diagnosed diabetes in the United States was estimated to be $327 billion, including $237 billion for direct medical costs and $90 billion in reduced productivity.[2] Additionally, medical expenditures for people with diagnosed diabetes are 2.3 times higher on average than what expenditures would be in the absence of diabetes.[2]

Despite advancements in diabetes care and treatment, findings from the 2005-2016 National Health and Nutrition Examination Survey (NHANES) showed that there has been no significant improvement in the achievement of targets for diabetes treatment.[3] The successful management of diabetes requires the patient to have a strong understanding of the impact of diet, lifestyle, and treatment on their glycemic control. Through ongoing patient self-management education and support, patients can be empowered to make good diabetes treatment decisions that are critical to preventing acute complications of diabetes and reducing the risk of long-term complications.[4]

The patient's ability to self-manage is especially important when it comes to using insulin treatments. Patients with type 1 diabetes must take insulin to survive, and many patients with type 2 diabetes also require insulin supplementation in order to control persistent hyperglycemia.[4] However, because of the challenges of insulin therapy, patients with type 2 diabetes often do not receive insulin or do not receive it in a timely manner.[5]

Selvin and colleagues reported that the proportion of patients with diabetes currently on any insulin (including insulin only and insulin plus oral diabetes medications) was 29.1% in 2005–2012.[5] Unfortunately, glucose control has been shown to be inadequate among insulin-treated patients, in part because of insulin omission or nonadherence.[6]

In a survey study of 1530 insulin-treated patients in China, France, Japan, Germany, Spain, Turkey, United Kingdom, or United States, 33.2% of patients reported insulin omission or non-adherence for at least 1 day in the previous month, with an average of 3.3 days.[6]

The same survey study included 1250 physicians who treat patients with diabetes, most of whom reported that many insulin-treated patients do not have adequate glucose control (87.6%) and that they would treat more aggressively if not for concerns about hypoglycemia (75.5%).[6]

Helping patients to understand and overcome the factors that contribute to insulin omission or nonadherence is essential, as these factors are preventing them from achieving their glycemic goals.

Hypoglycemia as a Complication of Treatment

Hypoglycemia is the major limiting factor in the glycemic management of type 1 and type 2

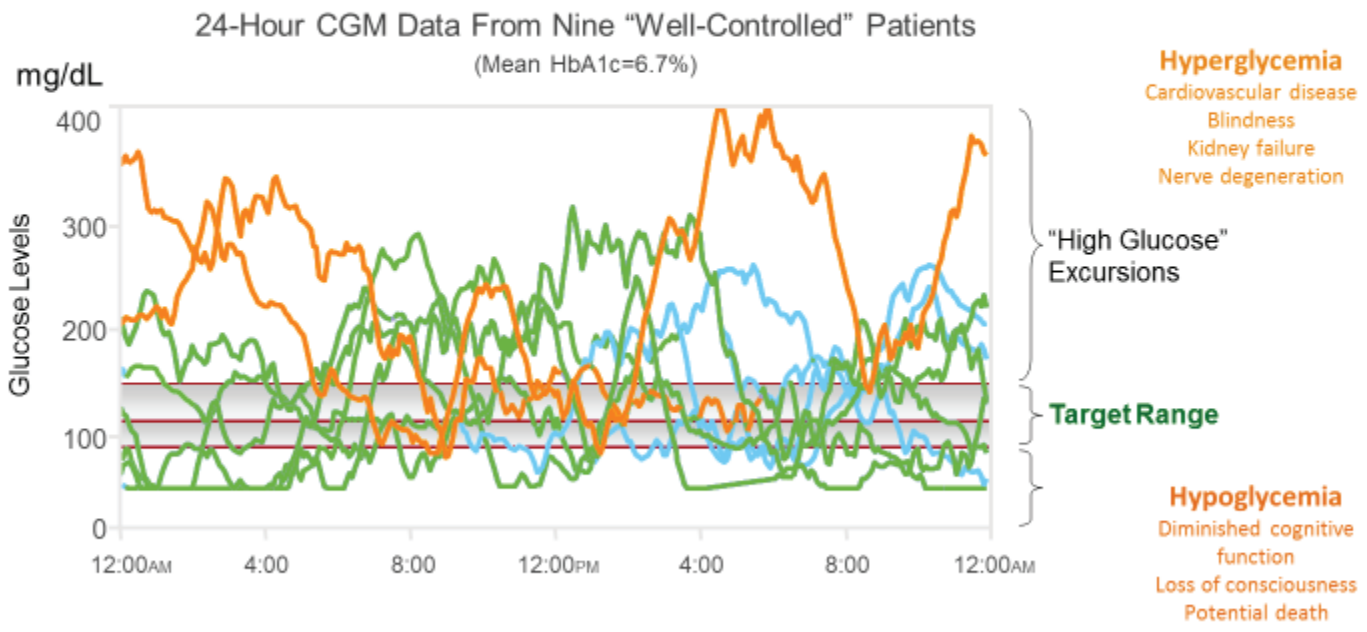

Figure 1. Limitations of A1C as a Measure of Glycemic Control. 24-hour CGM data from nine patients with a mean A1C of 6.7% still demonstrate glucose levels outside of the target range, including hyperglycemia and hypoglycemia.[4,7]

diabetes.[7,8] Hypoglycemia includes all episodes of an abnormally low plasma glucose concentration that expose the individual to potential harm.[7,8] The majority of hypoglycemic episodes experienced by patients with diabetes are related to medication.[9]

The short- and long-term complications of diabetes-related hypoglycemia include precipitation of acute cerebrovascular disease, myocardial infarction, neurocognitive dysfunction, and retinal cell death and loss of vision. These are in addition to health-related quality of life (QOL) issues pertaining to sleep, driving, employment, recreational activities involving exercise, and travel.[9]

Regardless of whether a patient has type 1 or type 2 diabetes, the use of medications such as insulin can lead to hypoglycemia. There is an urgent need to examine the clinical spectrum and burden of hypoglycemia so that adequate control measures can be implemented against this under-addressed life-threatening complication.[9]

If untreated, non-severe hypoglycemia may further progress to severe hypoglycemia. Severe hypoglycemia is defined as an event requiring assistance of another person to actively administer carbohydrates, glucagon, or take other corrective actions.[4] It may be recognized or unrecognized and can progress to loss of consciousness, seizure, coma, or death.[4]

Some patients are able to rely on the symptoms of hypoglycemia—which include shakiness, irritability, confusion, tachycardia, and hunger[4]—to take action and self-treat by ingesting glucose. However, most episodes of hypoglycemia and severe hypoglycemia occur nocturnally[9] when patients are the most vulnerable and unable to use traditional methods of self-monitoring of blood glucose (SMBG) with fingersticks.[9] Technology, such as continuous glucose monitoring (CGM), is available to help patients who require support for the management of their diabetes.

Patients who frequently experience hypoglycemia may have a maladaptive response whereby they do not have symptoms accompanying the fall in blood glucose levels until they become lower and lower; thus, these patients may not be aware of their hypoglycemia.[8] This condition is known as hypoglycemia unawareness (or hypoglycemia-associated autonomic failure) and can severely compromise stringent diabetes control and QOL.[8,9] Hypoglycemia unawareness also increases a patient's risk for severe hypoglycemia 6-fold and 9-fold in patients with type 1 and type 2 diabetes, respectively.[10,11]

Due to patients' impaired awareness of hypoglycemia, and of the fact that most hypoglycemic episodes occur nocturnally, hypoglycemia is underreported to health care providers and frequently results in a significant adverse event requiring emergency department (ED) care or hospital admission.[9-12]

In the United States annually, insulin-related hypoglycemia is responsible for 100,000 ED visits, with approximately one-third of the ED visits resulting in a hospitalization.[12]

The impact of hypoglycemia and severe hypoglycemia is likely much higher than what is reported; a Kaiser survey showed that medical records only captured 1 in 20 severe hypoglycemic events reported by patients.[13]

Due to the severe consequences of hypoglycemia—including death—many patients become fearful of hypoglycemia; that is, they

would rather remain hyperglycemic than be exposed to the risks of hypoglycemia. Because fear of hypoglycemia has been shown to hinder adherence to insulin regimens, the American Diabetes Association (ADA) recommends referral to a mental health provider for these patients.[4] This underscores the support needed by insulin-using patients, who are the most at risk for hypoglycemia.

Hypoglycemia and fear of hypoglycemia have a significant impact on QOL, workplace absenteeism, and productivity in patients with both type 1 and type 2 diabetes.[8,9] A survey assessing the impact of non-severe hypoglycemic events (NSHEs) was administered to individuals 18 years of age or older with self-reported diabetes in the United States, United Kingdom, Germany, and France. Of 1400 responders with NSHEs that occurred outside of working hours, including nocturnal events, 22.7% were late for work or missed a full day of work.[14] Productivity loss was highest for participants whose NSHEs occurred during sleep, with an average of 14.7 working hours lost. In the week following an NSHE, respondents required an average of 5.6 extra blood glucose test strips, and insulin users decreased their insulin dose by 25%, reflecting fear of hypoglycemia affecting their treatment decisions with insulin.[14]

Admission for dysglycemia is a strong predictor of a readmission within 30 days due to dysglycemia,[15-17] and both NSHE and severe hypoglycemia events are associated with a higher risk of cardiovascular events, hospitalization, and all-cause mortality.[18,19] In the DEVOTE trial of patients with type 2 diabetes, there was a 2.5-fold greater risk of death after an episode of severe hypoglycemia, with the risk being 4-fold higher in the 15 days following an event.[20]

Importance of Glucose Monitoring

Glucose monitoring is an essential component of successful diabetes management,[4] particularly for patients at risk for hypoglycemia.[4,7]

Many clinicians use glycated hemoglobin (A1C) to measure an average glucose level for the patient over the previous 2-3 months. This is used to establish treatment goals, assess glycemic control, and predict the risk of developing long-term complications.[21]

Unfortunately, A1C treatment goals are not being met despite advancements in diabetes care and treatment, because many providers and patients do not have enough daily glucose information to effectively utilize treatments that can lower A1C without putting the patient at risk for hypoglycemia. Although A1C is a valuable measure of glycemic control at the population level, it has limitations that hinder its usefulness in daily diabetes self-management,[21] and it may not be a good indicator of an individual patient's glycemic control (**Figure 1**) because it does not provide a measure of hypoglycemia and hyperglycemia on a daily basis.[22] Most importantly, A1C does not provide guidance for daily adjustments in therapy.[21]

Patient SMBG with fingersticks is an integral component of effective therapy and allows patients to evaluate their individual responses to therapy and assess whether glycemic targets are being achieved.[4] However, the value of SMBG is dependent on how well the patient complies with recommendations for testing frequency and whether any action is taken based on the results.

Real-world evidence from the T1D Exchange Clinical Registry shows patients are inadequately testing (on average four times per day with one-third of patients testing zero to three times daily). This is in contrast to the ADA recommendations for patients on intensive insulin (three or more insulin injections per day or insulin administered through a pump) to test six or more times per day.[4,23]

Additionally, SMBG only measures glucose at a single point in time, which provides no indication of the direction (trending up, down, or flat) or rate of change in glucose, and because waking up at night to test is impractical for many patients, it is not useful to detect nocturnal hypoglycemia.[21]

SMBG can be painful, inconvenient, and thus underutilized. This leads patients and their providers to make treatment decisions without quality glucose information, contributing to the short-term (eg, hypoglycemia) and long-term complications of poorly controlled diabetes.[24]

New metrics that are readily accessible for patients and providers are needed to determine whether glycemic control is being achieved on a daily basis and to provide insight on the impact of diet, lifestyle, and treatment on glucose levels.

A consensus panel identified "time in range" (TIR) as a metric of glycemic control that provides more actionable information than A1C alone. The establishment of target percentages of time in the various glycemic ranges can facilitate safe and effective therapeutic decision-making within the parameters of the established glycemic goals.[25]

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The metric includes three key CGM measurements: percentage of readings and time per day within target glucose range of 70-180 mg/dL (TIR); time below target glucose range of 70 mg/dL (TBR); and time above target glucose range of 180 mg/dL (TAR).[25] For most patients, the primary goal for effective and safe glucose control is to increase the TIR to 70% or more per day while reducing the TBR to 4% or below per day.[25]

Unlike A1C measurement, use of these CGM metrics allows for the direct observation of glycemic excursions and daily profiles, which can inform immediate therapy decisions and lifestyle modifications. These metrics also provide the ability to assess glucose variability and identify patterns of hypo- and hyperglycemia.[25]

TIR, TBR, and TAR are important measures that cannot be assessed with SMBG and can only be measured with CGM.[25] These CGM metrics and goals are highly relevant and clinically important, and the recommendations for their use have been endorsed by the ADA, American Association of Clinical Endocrinologists, American Association of Diabetes Educators, European Association for the Study of Diabetes, Foundation of European Nurses in Diabetes, International Society for Pediatric and Adolescent Diabetes, JDRF, and Pediatric Endocrine Society.[25]

Using the IQVIA Core Diabetes Model, improvements in TIR were estimated to reduce the risk of developing diabetes-related complications, such as myocardial infarction, end-stage renal disease, severe vision loss, and amputation, resulting in an initial conservative estimated reduction of $6.7–9.7 billion in costs over a 10-year period.[26]

One study evaluated the association of TIR of 70–180 mg/dL (3.9–10 mmol/L) with the development or progression of retinopathy and development of microalbuminuria using the Diabetes Control and Complications Trial data set, in order to validate the use of TIR as an outcome measure for clinical trials.[27] Spending less time in an optimal glycemic range was shown to be associated with poor outcomes. For each 10 percentage points lower TIR, the hazard ratio of development of retinopathy progression was increased by 64% (95% CI: 51-78), and development of the microalbuminuria outcome was increased by 40% (95% CI: 25–56; $P < .001$ for each). Results were similar for mean glucose and hyperglycemia metrics.[27] Based on these results, a compelling case can be made that TIR is strongly associated with the risk of microvascular complications and is an important clinical outcome measure.[27]

CGM Systems

CGM is a method of continuously following glucose levels in the interstitial fluid as a basis for improving metabolic control, including increasing TIR.[28] Multiple CGM devices have been approved by the Food and Drug Administration (FDA), but there are notable differences within the category. These differences have been clarified by the European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group, which defines CGM systems as either real-time or intermittently scanned.[27]

A real-time CGM (rtCGM) device (eg, Dexcom G6) passively—that is, without any action by the user—provides glucose data, including rate and direction of glucose changes, continuously to a receiver, smart watch, or smart phone that the wearer can view in real time, allowing for alerts and active alarms to be provided when glycemic thresholds are crossed.[29]

With intermittently scanned CGM (isCGM) devices (eg, Abbott FreeStyle Libre), interstitial glucose levels are measured continuously, but data are not transmitted continuously from the sensor, and the results are only available when the user takes an action to scan the sensor with a reading device. In the United States, isCGMs (also known as "flash" CGM outside the United States) do not have real-time alerts or alarms.[28]

Dexcom G6

The FDA approved the Dexcom G6 integrated CGM (iCGM) system in 2018 for determining glucose levels in children aged 2 years of age and older and adults with diabetes to be used as a replacement for fingerstick testing to make diabetes treatment decisions.[30]

This is the first type of CGM system permitted by the agency to be used on its own or as part of an integrated system with other compatible medical devices and electronic interfaces; these may include automated insulin dosing systems, insulin pumps, Bluetooth-connected insulin pens or other electronic devices/apps used for diabetes management.[30]

The FDA authorization of the G6 device as an iCGM system subjects it to certain criteria called special controls that provide assurances of safety and effectiveness.[30] The FDA recognized this as an opportunity to reduce the regulatory burden for iCGM by establishing criteria that would classify iCGM as "moderate risk" class II medical devices with special controls vs other CGMs that are class III "highest risk" devices.[30] The Dexcom G6 system is currently the only device that meets the FDA's criteria for this iCGM category.[30]

The Dexcom G6 is FDA approved for patient self-start. The patient uses a simple one-touch auto-applicator to insert a small, factory-calibrated, 10-day water-resistant sensor just beneath the skin of the abdomen that continuously measures the amount of glucose in interstitial fluid (**Figure 2**).[29]

The G6 transmits real-time glucose readings every 5 minutes to a small touch-screen receiver or a compatible display device, such as a medical app on a mobile phone, to display real-time glucose data.

The CGM data can also be shared with up to 10 followers who will receive the user's glucose data in real time with alerts and alarms, who can then check on or assist the user if needed.

The G6 also triggers an alert or alarm when a patient's blood sugar is trending high or low, allowing the user (or a follower) to take action to treat or prevent an actual or impending hypoglycemic/hyperglycemic event.

Users of the G6 can remotely allow their health care providers access to the last 90 days of their glucose readings via the diabetes management application CLARITY©, enabling telehealth and remote medical management opportunities. CLARITY provides a complete glucose dataset to providers and patients so that they can identify glucose trends and patterns to assist in optimizing the diabetes management plan. This can be especially helpful for patients who are homebound or live in areas that do not have specialists within close proximity.

With the latest G6 app update, patients using certain iOS devices (those using iOS 12 and above and supported Apple Watches and watchOS) can ask Siri to audibly recite the Dexcom glucose readings with rate and direction out loud and display them in a graph directly on the lock screen.[31] This can be especially useful in situations such as driving when a patient cannot view their glucose readings on their device.

Clinical Studies of CGM

Evidence for the clinical benefits of rtCGM comes from randomized controlled trials, patient-reported outcomes, and observational studies. Several trials have compared outcomes such as A1C reduction and hypoglycemia mitigation for rtCGM users compared with usual care with SMBG.[32,33] Details on select clinical trials are provided in the **Table**.

In the DIAMOND (Multiple Daily Injections and Continuous Glucose Monitoring in Diabetes) randomized clinical trials, patients using multiple daily injections of insulin with type 2 diabetes and with type 1 diabetes who were randomly assigned to rtCGM had improved glycemic control vs SMBG users.[34,35] In both type 1 and type 2 studies, this benefit was seen across patient groups regardless of baseline A1C, age, education level, or math ability. In addition, rtCGM was associated with increased TIR (70-180 mg/dL).[34,35]

(A)

(B)

(C)

(D)

Figure 2. G6 Device. (A) G6 Sensor and Applicator. (B) G6 Transmitter. (C) G6 Receiver and Smart Device with G6 Mobile Application. (D) Sensor and Transmitter on Patient.

Table. Randomized Clinical Trials of CGM

Study Name	Patient Population	Design	Outcome(s) of Interest	Results
DIAMOND Type 2[28]	Adults Type 2 diabetes A1C 7.5% to 9.9%	Randomized 1:1 to CGM (n = 79) or usual care (n = 79) for 24 weeks	A1C reduction	Adjusted difference in mean A1C change, −0.3% [95% CI, −0.5% to 0.0%]; *P* = .022]
DIAMOND Type 1[29]	Adults Type 1 diabetes A1C 7.5% to 9.9%	Randomized 2:1 to CGM (n = 105) or usual care (n = 53) for 24 weeks	A1C reduction	Adjusted difference in mean A1C change, −0.6% [95%CI,−0.8% to −0.3%; *P* < .001]. Significant reduction in hypoglycemia in the CGM group.
GOLD[31]	Adults Type 1 diabetes A1C ≥7.5%	Crossover design, randomized 1:1 to CGM before (n = 82) or after (n = 79) conventional treatment for 26 weeks with a 17-week washout between treatment periods	A1C reduction	Mean A1C difference, −0.43% [95%CI, −0.57% to −0.29%; *P* < .001]. Significant reduction in hypoglycemia in the CGM group.
HypoDE[32]	Type 1 diabetes History of impaired hypoglycemia awareness or severe hypoglycemia during the previous year	28 days of masked real-time CGM + 1:1 randomization to unmasked real-time CGM (n = 75) or self-monitoring of blood glucose (n = 74) for 26 weeks	Hypoglycemia reduction	Incidence of hypoglycemic events decreased by 72%; incidence rate ratio 0.28 [95% CI 0.20–0.39; *P* < .0001]
I HART CGM[33]	Type 1 with impaired awareness of hypoglycemia or recent severe hypoglycemia	Randomized 1:1 to CGM (n = 20) or flash glucose monitoring for 8 weeks	Hypoglycemia reduction	Median between group difference in time spent in hypoglycemia (<60 mg/dL), -4.3% [*P* = .006] CGM reduces hypoglycemia more effectively than flash glucose monitoring.
COMISAIR[34]	Type 1 diabetes On insulin treatment [multiple daily injections [MDI] or continuous subcutaneous insulin infusion [CSIII]] A1C 7.0% to 10.0%	3-year, nonrandomized, prospective, real-world, clinical trial followed 94 participants with T1D (rtCGM+MDI, n=22; rtCGM+CSII, n=26; SMBG+MDI, n=21; SMBG+CSII, n=25)	A1C reduction Hypoglycemia reduction Time in range (70–180 mg/dL) Time below range (<70 mg/dL)	At 3 years, the rtCGM groups (rtCGM+MDI and rtCGM+CSII) had significantly lower A1C (7.0%, P= 0.0002, and 6.9%, P < 0.0001, respectively), compared with the SMBG+CSII and SMBG+MDI groups (7.7%, P = 0.1.000, and 8.0%, P = 0.3574, respectively). Significant improvements in percentage of time in range were observed only in the rtCGM subgroups Significant reductions in time below range

In the type 1 diabetes study, the rtCGM group spent 79% less time in nocturnal hypoglycemia (<60 mg/dL) and also demonstrated a greater increase in hypoglycemic confidence (*P* = .01) and a greater decrease in diabetes distress (*P* = .01) than the SMBG group. CGM satisfaction was not significantly associated with glycemic changes but was associated with reductions in diabetes distress (*P* < .001) and hypoglycemic fear (*P* = .02) and increases in hypoglycemic confidence (*P* < .001) and well-being (*P* = .01).[35,36]

In the GOLD trial, glycemic control was improved during rtCGM compared with conventional treatment; however, increases in A1C and hypoglycemic events occurred when patients reverted back to SMBG during the crossover/washout period, suggesting that the effectiveness of CGM depends on uninterrupted use during treatment with multiple daily insulin injections (MDI). Additionally, the study showed reductions in severe and nocturnal hypoglycemia as well as in glycemic variability and hypoglycemic confidence for CGM users.[37]

The HypoDE study was a multi-center, open-label, randomized controlled trial conducted in adults with type 1 diabetes and hypoglycemia unawareness or severe hypoglycemia using MDI. The study showed use of rtCGM reduced the number of severe hypoglycemic events by 72% compared with SMBG.[38]

The I HART CGM randomized controlled trial assessed the impact of rtCGM versus isCGM on hypoglycemia in high-risk type 1 diabetes patients who had experienced a severe hypoglycemic event in the 12 months prior to the study or who had hypoglycemia unawareness. The study found that percent time in hypoglycemia (<63 mg/dL) decreased from 4.5% to 2.4% for rtCGM users, while it increased from 6.7% at baseline to 6.8% for isCGM users (between group difference, *P* = .006).[39] The study authors suggested that the alerts/alarms available with rtCGM led to the hypoglycemia reductions seen in that group.[39]

The HypoDE and I HART studies are especially notable because they showed that only rtCGM, and not isCGM, decreases hypoglycemic events and fear of hypoglycemia in the highest risk type 1 patients with impaired awareness of hypoglycemia or severe hypoglycemia.[38,39]

Real-World Studies

The COMISAIR study is the longest running real-world rtCGM study performed to date. The study assessed the clinical impact of four treatment strategies in adults with type 1 diabetes: rtCGM with MDI (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) over a 3-year time period.[40,41] In this study, the continuous use of rtCGM had a sustained and durable benefit with regards

to glycemic control over a 3-year time period, with rtCGM being superior to SMBG in reducing A1C, hypoglycemia, and glycemic variability in individuals with type 1 diabetes regardless of their insulin delivery method.[40,41]

The T1D Exchange Clinic Registry follows over 26,000 patients with type 1 diabetes, almost 15,000 of whom are younger than 18 years of age. Recent Registry data have confirmed that rtCGM use is increasing rapidly, especially among very young children.[23,42] In every age cohort examined, rtCGM use has been associated with lower A1C values. With regards to acute complications of diabetes, CGM users in all age groups reported significantly lower diabetic ketoacidosis and fewer severe hypoglycemic events vs non-CGM users.[23,42]

The RESCUE study assessed the impact of rtCGM on adults with type 1 diabetes on CSII therapy in a prospective, observational, multicenter, cohort real-world study with a total of 515 participants.[43] Those who started real-time CGM because of insufficient glycemic control showed greater decreases in A1C at 4, 8, and 12 months compared with patients who started because of hypoglycemia or pregnancy.[43] In the year preceding rtCGM reimbursement, 16% of patients were hospitalized for severe hypoglycemia or ketoacidosis in contrast to 4% the following year, with a decrease in admission days from 54 days to 18 days per 100 patient-years ($P = .0005$).[43] In the same period, work absenteeism decreased and QOL improved significantly, with strong decline in fear of hypoglycemia.[43]

A real-world study investigated the efficacy and safety of rtCGM initiation within 1 year of type 1 diabetes diagnosis among children, adolescents, and adults seen at the Barbara Davis Center for Diabetes.[44] Differences in mean A1C (primary outcome) and diabetes-related ED visits (secondary outcome) for 2.5 years between early CGM users and non-CGM users were studied.[44] Among 396 newly diagnosed patients with type 1 diabetes, irrespective of insulin delivery methods, CGM users had a significantly greater improvement in glycemic control than non-CGM users, and the number of diabetes-related (severe hypoglycemia or hyperglycemia) ED visits was significantly lower among early CGM users compared with non-CGM users.[44]

Benefits of Alarm and Alert Features

Real-time alerts and alarms can notify users of hypoglycemia, hyperglycemia, and rapidly falling or rising glucose without an action by the user so they can be alerted to dangerous lows or highs without having to look at a receiver. These alerts and alarms are potentially lifesaving for insulin-using patients who are at an increased risk for nocturnal hypoglycemia and hypoglycemia unawareness.[32]

The glucose information and safety features of alerts/alarms and sharing provided by rtCGM are allowing many people with insulin-requiring diabetes to set and reach more aggressive glycemic goals.[32] Differences between the features of CGM devices, including alerts and alarms, can play a major role in influencing both patient and clinical satisfaction and confidence in using CGM as a component of diabetes management.

Studies have shown that patients are more likely to use rtCGM when they believe that the device and the resulting data can be trusted to accurately reflect worrisome, out-of-range glucose levels and when they are not subjected to frequent alarms that turn out to be false. Greater confidence in the accuracy of the data may lead those patients who are more "reactive" users (responding only to alerts and alarms) to engage more frequently with the device and become "proactive" users, wielding the numerical and trend data to anticipate glucose changes and respond early and aggressively.[45]

One type of clinically relevant and accurate alert unique to the G6 system is a predictive "Urgent Low Soon" alert, which can warn patients and their caregivers of hypoglycemic events before neuroglycopenia develops.[46] The alert is enabled by default and triggered when an estimated glucose value of 55 mg/dL or less is predicted in the next 20 minutes.[46] A study examined whether a predictive low glucose alert could provide additional advance warning to rtCGM users before the onset of clinical hypoglycemia. Estimated glucose values from an anonymous convenience sample of 1424 patients before and after their transition from the G5 system (without predictive alerts) to the G6 system were evaluated. The transition to G6 was associated with significantly reduced biochemical (<70 mg/dL) and clinical (<54 mg/dL) hypoglycemia. Compared with intervals of G5 use, the extent of clinical hypoglycemia fell by 40.0% and 33.3% during G6 use for users with a low threshold setting of 70 mg/dL and 80 mg/dL, respectively.[46]

The Dexcom Share Feature

The Dexcom Share feature allows users to select up to 10 designated recipients, or "followers," who can remotely monitor the user's glucose information and receive alert notifications when glycemic thresholds are crossed for added protection and peace of mind.

Prior to CGM with alerts and alarms, many caregivers would test their loved ones throughout the night due to worry of finding them "dead in bed" due to a hypoglycemic episode, having a negative impact on QOL both for the patient and caregiver.[9]

Remote monitoring capabilities provide many parents of children with diabetes the opportunity to unobtrusively follow their child's glucose levels throughout the day and night. This feature is also useful for older individuals who may not be able to reliably measure their own blood glucose values and make insulin dosing decisions on their own.[47]

In a randomized crossover study to explore the effect of rtCGM with remote monitoring on psychosocial outcomes in parents of children with type 1 diabetes, children used conventional blood glucose monitoring or Dexcom CGM with remote monitoring over two 3-month periods. Parental Hypoglycemia Fear Survey scores were lower for parents of children using CGM with remote monitoring ($P < .001$). Furthermore, parental health-related QOL and family functioning, stress, anxiety, and sleep measures also improved significantly after intervention.[48]

In a retrospective evaluation of device usage and glycemic control in 15,000 youth ranging in age from 2 to 18 years, 94.8% of the population used the sharing feature and had at least one follower.[48] The presence of a follower was associated with lower mean glucose values, a greater number of glucose vales in the 70-180 mg/dL range, correspondingly fewer glucose values representing hypoglycemia and hyperglycemia, and significantly higher device utilization.[49]

CLARITY System

Dexcom CLARITY is a data management software program that allows users to upload glucose

Figure 3. Process for Patient Access to a CGM Device Through the DME Channel vs the Pharmacy Channel.

data from a Dexcom CGM device and then view the data in easy-to-read graphs with trends, statistics, and day-by-day data and then remotely share the information with their health care provider.

The cloud-based Dexcom CLARITY software is intended for use by both home users and health care providers to assist people with diabetes in the review, analysis, and evaluation of historical CGM data to support effective diabetes management. The software provides summary reports, which include average glucose, frequency of calibrations, and patterns of low and high glucose. Health care providers can use the retrospective information presented in Dexcom CLARITY to modify their treatment and recommendations for a patient's diabetes management plan.

An analysis of 50,000 users showed that patients who logged in to CLARITY four or more times in 1 month had significantly higher TIR of up to 15%, lower mean sensor glucose values, and less time in hyperglycemia than patients who did not log in during the same time interval.[50]

Reimbursement and Access

The benefits of CGM for the management of diabetes have been established. Clinical trials and real-world evidence have demonstrated the value of starting CGM as early as diagnosis to maintain glycemic control and avoid complications that could lead to ED visits, rather than using SMBG, which has been shown to be inferior to CGM with regards to glycemic control and hypoglycemia reduction.

Additionally, the evidence demonstrates that rtCGM use, rather than the insulin delivery method (MDI or pump), is the contributing factor to reducing A1C, increasing TIR, and reducing time spent in hypoglycemia. Therefore, regardless of whether the patient has type 1 or type 2 diabetes, the use of insulin can put the patient at risk for complications of diabetes treatment, necessitating rtCGM technology.

Recognizing the value of CGM, and in response to the recent FDA approvals of CGM as a replacement for fingersticks, the Centers for Medicare and Medicaid Services (CMS) created a ben fit category for therapeutic CGMs, providing for coverage of these devices under the following conditions:[51]

- The beneficiary has type 1 or type 2 diabetes;
- The beneficiary has been using a blood glucose meter (BGM) and performing frequent (four or more times a day) testing;
- The beneficiary is insulin-treated with MDI or an insulin pump;
- The insulin regimen requires frequent adjustment on the basis of BGM or CGM testing results;
- Within 6 months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria are met; and,
- Every 6 months following the initial prescription of CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM and treatment plan.

Because Dexcom CGM is approved by the FDA as a replacement for fingersticks to make diabetes treatment decisions, CMS has designated Dexcom rtCGM as meeting coverage criteria for therapeutic CGM.[51]

Currently, payer coverage is mostly for patients with type 1 diabetes through the medical or durable medical equipment benefit (DME), but the evidence and guidelines state that patients with type 2 diabetes who are on intensive insulin (3 or more injections or insulin via pump) can also benefit from CGM.[52-57] Payers should consider aligning their CGM coverage policies with CMS criteria.

Payers should also consider making CGM available through the pharmacy benefit vs a DME supplier. The advancements and evidence for CGM devices are at a point where it is ideal that patients and providers be able to access and prescribe

CGM using a patient's pharmacy benefit, where they also get their medications and other supplies for diabetes and other illnesses (**Figure 3**). This will better allow patients to readily start CGM and safely and effectively use their treatments to avoid complications of diabetes management. With coverage of CGM through the pharmacy benefit, a patient can get a CGM within days vs weeks on the medical benefit, improving outcomes and reducing costs. For example, prescribing CGM to patients upon discharge from the hospital due to a diabetes related complication can be implemented to prevent a readmission and aid transitions of care to the ambulatory setting.

The pharmacy benefit is where providers and patients are most comfortable accessing the supplies and treatments they need to manage diabetes, offering enhanced convenience and patient support. The pharmacist is able to further engage and support patients to recommend CGM and use objective real-time glucose data, which can contribute to the successful management of diabetes.

Recent reviews have shown that pharmacist involvement in diabetes self-care interventions prove to be cost-effective and can significantly affect the condition of diabetic patients and reduce the risk of complications.[58,59] Pharmacist interventions have demonstrated improvements in A1C, blood pressure, cholesterol levels, body mass index, and 10-year cardiovascular risk.[59]

By improving coverage for CGM for type 1 and type 2 patients and allowing access through the pharmacy benefit, there is an opportunity for patients and providers to successfully manage a disease where the direct costs of complications (hospitalizations, ER visits, medications) and indirect costs (lost or reduced productivity) account for greater than 73% of the $327 billion spent on diabetes in the United States in 2017.[60]

Conclusions

For patients who experience nocturnal hypoglycemia and/or hypoglycemia unawareness, the alert/alarm function of rtCGM devices may be their only warning of emerging hypoglycemia. In contrast, traditional fingerstick SMBG, which provides intermittent and limited information about blood glucose concentrations at single points in time, may fail to detect potentially dangerous glycemic excursions even when diligently performed.[61,62] There is evidence that current-generation rtCGM therapy is cost effective in the short term by reducing the incidence of costly emergency medical treatmentof severe hypoglycemia[63] and in the long term by decreasing the risk of microvascular and macrovascular complications.[64]

Because of this, rtCGM is becoming the standard of care for insulin-treated patients with poorly controlled diabetes.[52-57] The FDA approval for the G6 as a replacement for SMBG with no calibration and for integration with compatible medical devices demonstrated the rapid evolution and importance of this technology.[30]

Based on the evidence, requiring SMBG use before covering CGM exposes type 1 and type 2 patients to the risks of uncontrolled diabetes and adverse effects of treatment. From an access perspective, having CGM available through the phamacy benefit will help patients avoid delay when starting CGM and utilize pharmacists to help them be successful in the management of a difficult chronic disease and avoid costly complications. Additionally, limiting coverage to type 1 patients does not recognize the challenges that type 2 patients on intensive insulin face and exposes them to the long-term complications of poor control and the potentially severe consequences of hypoglycemia.

A statement from the principles of the American Association of Clinical Endocrinology and the American College of Endocrinology comprehensive type 2 diabetes management algorithm states, "Minimizing risk of both severe and non-severe hypoglycemia is a priority. It is a matter of safety, adherence, and cost."[55]

Diabetes is a complex and challenging disease that requires patients to make hundreds of decisions per day.[65,66] The use of CGM provides unprecedented information to educate and empower patients and providers on how often one experiences hyperglycemia, hypoglycemia, and in-range glucose values along with the impact of diet, lifestyle, and treatment decisions to enable the prevention of the short- and long-term complications of diabetes.[65]

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‡For a list of compatible devices, visit dexcom.com/compatibility.

[1]FreeStyle Libre 14 day Flash Glucose Monitoring System User's Manual, 2018.

BRIEF SAFETY STATEMENT Failure to use the Dexcom G6 Continuous Glucose Monitoring System (G6) and its components according to the instructions for use provided with your device and available at https://www.dexcom.com/safety-information and to properly consider all indications, contraindications, warnings, precautions, and cautions in those instructions for use may result in you missing a severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) occurrence and/or making a treatment decision that may result in injury. If your glucose alerts and readings from the G6 do not match symptoms, use a blood glucose meter to make diabetes treatment decisions. Seek medical advice and when appropriate, including for any medical emergency.

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