I. Introduction

Diabetes is one of the great scourges of our time, accounting for significant morbidity and mortality, and diminished quality of life for masses of affected individuals and their families. (1,2,3) (Ia, A) Meanwhile, the value of achieving normoglycemia (or near-normoglycemia) is well-established. (4,5,6,7) (Ia, A) To that end, many medical organizations have established aggressive targets for glycemic control in individuals with Type-1 and Type-2 diabetes.(8,9) However, our ability to meet these targets without undue hypoglycemia continues to elude us: HbA1c levels are above target in the majority of people with diabetes, and severe hypoglycemia remains an ongoing threat to personal safety and well-being.(10-16) (IIa, B) What’s more, analysis of glucose levels, even in “well-controlled” patients with Type-1 or Type-2 diabetes, indicates that significant time is spent above and below desired target ranges. (17,18) (IIa, B)

The tools traditionally used to treat and manage diabetes limit our ability to meet glycemic goals. Point-in-time (fingerstick) blood glucose measurements can be particularly problematic. These readings, typically taken four times daily in those patients on multiple daily doses of insulin, fail to provide key information regarding the context (i.e. direction and recent history) of the blood glucose level. In most cases, they also fail to provide sufficient warning of pending hypoglycemia or severe hyperglycemia, thus limiting the patient’s ability to take evasive action. For our patients with diabetes, this is similar to reading only the first page of each chapter of a book. They receive select bits of information, but the full story and the all-important details are missing. (19, 20) (IV, D)

Now we have an opportunity to learn the full story. “Real-Time” Continuous glucose monitors (CGMs) display updated glucose information every few minutes from subcutaneous interstitial fluid using sensors that can be used for 3-7 days. They also produce trend graphs and alarms to warn the user of pending high or low glucose levels. “Professional” CGM systems are worn for a fixed period of time with the user blinded to the data. Downloadability of both “Real Time” and “Professional” CGM permits retrospective analysis of large sums of data, allowing the user and their healthcare team to generate statistics and detect patterns/trends that facilitate therapeutic adjustments. All further discussion will focus on the use of Real-Time continuous glucose monitoring.
The CGM systems that are commercially available utilize a thin metallic filament inserted just below the skin to detect glucose in the subcutaneous interstitial fluid. The information from the sensor is transmitted via radio signals to a handheld receiver/display. Occasional calibration by way of fingerstick blood glucose readings is required. The systems are generally accurate to within 10-20% of most fingerstick values. Specific attributes of glucose sensors are well-reviewed in an article by Oliver. (21)

II. Justification / indications for Use

When it comes to intensive diabetes management, information is power. Traditional forms of glucose monitoring provide insufficient information for achieving glycemic goals in a safe manner. CGM provides immediate, ongoing feedback that the user can apply towards reaching desired goals.

The clinical value of Continuous Glucose Monitoring is well-documented.(see figure below (22)).(23-29) (Ib, A)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Ages</th>
<th>Description</th>
<th>Outcomes</th>
</tr>
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<tbody>
<tr>
<td>STAR 3</td>
<td>Age 7-18</td>
<td>MDI users either maintained on MDI or transitioned to Insulin Pump with integrated CGM.</td>
<td>In adult and youth groups, at 12 months, A1c levels dropped significantly more for Pump/CGM users than for MDI users (-1.0% vs -.4% for adults, -.4% vs +.2% for youth). Improvement in A1c started at 3 months and continued for 12 months for both adult and youth groups. Percentages of adults and youth reaching A1c &lt;7% were significantly greater in pump/CGM groups. No significant differences in severe hypoglycemia, DKA or weight gain between groups. Improvement in A1c proportionate to frequency of CGM usage.</td>
</tr>
<tr>
<td></td>
<td>Age 19+</td>
<td>Primary end point: HbA1c Secondary endpoint: Percentage with A1c &lt;7% and free of severe hypoglycemia, time spent in target glycemic range</td>
<td></td>
</tr>
<tr>
<td>STAR-1</td>
<td>Ages 12-72</td>
<td>Primary end point: HbA1c Also evaluated incidence of hyper/hypoglycemia</td>
<td>6-Month A1c, SMBG vs. SMBG &amp; CGM: no difference overall Those with &gt;60% time utilizing sensor: significant A1c reduction compared with less usage (p&lt;.05)</td>
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<tr>
<td>JDRF</td>
<td>Ages 12-72</td>
<td>Primary end point: HbA1c Also evaluated incidence of hypoglycemia</td>
<td>26 week analysis, use of CGM + SMBG (vs. SMBG alone) produced insignificant reduction in A1c (ages 15-24) Significant A1c reduction seen for ages 25+.</td>
</tr>
</tbody>
</table>
Hypoglycemia rates rare and similar in both groups
Frequency of CGM use was associated with significantly greater A1c reductions in all study groups

<table>
<thead>
<tr>
<th>Study</th>
<th>Group</th>
<th>Description</th>
<th>Findings</th>
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<tbody>
<tr>
<td>DirecNet Youth</td>
<td>Two 13-week pilot study</td>
<td>Primary end point: HbA1c Also evaluated incidence of hypoglycemia</td>
<td>Among insulin pump users, statistically significant reduction in HbA1c among CGM users. Insignificant difference in hypoglycemia frequency between groups.</td>
</tr>
<tr>
<td>JDRF CGM (2008)</td>
<td>Youth</td>
<td>26-Week randomized clinical trial Primary end point: HbA1c Also evaluated incidence of hypoglycemia</td>
<td>Pump and CGM users achieved A1c &lt;7% significantly more often than pump &amp; non-CGM users. Those who used the CGM at least 6 days/week maintained A1c improvement for 12 months. Insignificant difference in hypoglycemia frequency between groups.</td>
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</table>

In the recently-completed STAR-1, STAR-3, and DirecNet trials, CGM use produced improvements in HbA1c (less so for adolescents who used their CGM only intermittently) with simultaneous reductions in the frequency and severity of hypoglycemia in children with Type-1 diabetes and adults with Type-1 or Type-2 diabetes.

Severe Hypoglycemia and A1C: DCCT\(^{15}\) (1993), JDRF\(^2\) (2008), and STAR 3\(^{16}\) (2010) Studies

![Graph showing severe hypoglycemia and A1C relationship](image)

- **DCCT** (intensive therapy): 62 per 100 pt-yrs, A1C (6.5 yr): 9.0% → 7.2%
- **JDRF CGM**: 20.0 per 100 pt-yrs; A1C (6 mo): 7.5% → 7.1%
- **STAR 3 MDI** (all ages): 13.5 per 100 pt-yrs; A1C (1 yr): 8.3% → 8.1%
- **STAR 3 SAP** (all ages): 13.3 per 100 pt-yrs; A1C (1 yr): 8.3% → 7.5%

15. Adapted from Figure 5B of: DCCT. *N Engl J Med*. 1993;329:977-986.
Other studies have shown improvements in pregnancy outcomes (33) and duration of hypoglycemic episodes when low alerts were utilized. (34-39) (Ib, A)

In addition to these published studies, significant practical benefits have been observed in clinical practice. CGM serves as a valuable learning tool, showing patients the immediate impact of lifestyle and medicinal decisions. Responding in a timely manner to high- and low-glucose alerts significantly reduces glucose variability. Low alerts (and predictive low alerts, in some CGM models) are of particular value to Type-1 or Type-2 patients with hypoglycemia unawareness. They can also have an emotionally settling effect on the loved ones of people who use insulin and are subject to hypoglycemia.

The availability of ongoing glucose information can mean the difference between having to perform fingersticks 10-20 times daily and a more traditional four-times-a-day regimen for those susceptible to hypoglycemia. On-screen trend graphs and “direction arrows” allow users to forecast short-term changes to current glucose levels, thus improving decision-making capabilities. Retrospective analysis can allow clinicians to discriminate between traditional hyperglycemia and rebounds from hypoglycemia.

Based on published research and clinical observations, the American Association of Clinical Endocrinologists issued the following guidelines (22) in 2010:

On the basis of the available evidence, the American Association of Clinical Endocrinologists (AACE) recommends personal CGM for the following patients:

- Those with type 1 DM and the following characteristics:
  - Hypoglycemic unawareness or frequent hypoglycemia judged to be excessive, potentially disabling, or life-threatening
  - Excess glycemic variability
  - Requiring HbA1c reduction without increased hypoglycemia
  - During preconception and pregnancy

- Children and adolescents with type 1 DM who have achieved HbA1c levels less than 7.0% (these patients and their families are typically highly motivated)

- Youth with type 1 DM who have HbA1c levels of 7.0% or higher and are able to use the device on a near-daily basis

The following patients might be good candidates for personal CGM, and a trial period of 2 to 4 weeks is recommended:

- Youth who frequently monitor their blood glucose levels
- Committed families of young children (younger than 8 years), especially if the patient is having problems with hypoglycemia

In addition, hyperglycemia and hypoglycemia (40) pose significant risks within the hospital setting (41,42). The ability to achieve glycemic goals with fingerstick data is limited by inconsistent insulin action between different patients and varying levels of provider expertise in translating fingerstick data. Though none of the current CGM devices are approved for inpatient use, their potential seems enormous (43). Closed-loop systems (which include CGM) have been proposed as a key method to control hyperglycemia without undue hypoglycemia in the hospital. Mathematical algorithms would produce
more uniform responses to glycemic changes and would help to overcome biologic vagueries and human imprecision. Setting glucose targets to conservative levels would produce tight glycemic control without hypoglycemia, despite issues of sensor accuracy, lag-time and sensor site location. (45,46)

III. Practical Applications/ Benefits

When deciding whether or not to recommend CGM to a particular client, consider the potential uses for the system in both real-time and retrospective modalities.

(47, 48,49,50)

In real time

Use the high/low alerts

Low glucose alerts are valuable to anyone at risk for hypoglycemia, common in both type 1 and type 2 diabetes (51,52), but particularly those with impaired counterregulatory response to hypoglycemia (hypoglycemia unawareness), a condition which is much more common than previously recognized (14). Low alerts make it considerably safer for an insulin user to work, drive, exercise, and aim for tighter glycemic control. Likewise, the high alerts allow more aggressive management of after-meal glucose spikes, prevention of ketoacidosis, and lowering of the HbA1c.

Few patients can tell when blood glucose is slightly above or below target. CGMs provide a warning for mild hypo- and hyperglycemia earlier than patients could detect them on their own. Use of predictive alerts provides an even earlier warning. By instructing patients to act consistently upon receipt of high/low alerts (check blood glucose with a fingerstick and respond accordingly), the duration and extent of glucose excursions can be minimized. When responding to high alerts, it is imperative that “insulin-on-board” be considered. Otherwise, stacking of insulin could occur and lead to hypoglycemia.

Who benefits most: Those with hypoglycemia unawareness and/or elevated HbA1c

Adjust based on the immediate trends

In addition to short-term trend graphs, CGM systems provide directional “arrows” to indicate the recent rate of change in the glucose level. Knowing the direction, and not just the magnitude, of blood glucose can allow users to predict their glucose level for the next 30-60 minutes. This feature can facilitate better decision-making in terms of carbohydrate intake or supplementary insulin.

Prior to and during physical activity, a quick glance at the CGM receiver can provide users with invaluable insight to improve performance by optimizing glucose control. Conservative use of rapid-acting insulin can be used to reverse hyperglycemia and rising glucose levels, while rapid-acting carbohydrate can offset falling glucose levels and prevent hypoglycemia.

Patients who take rapid-acting insulin may also be advised to adjust their meal and correction boluses based on the direction the blood glucose is headed. Bolus insulin is intended to achieve normoglycemia in the next 3-4 hours; a current upward or downward trend will require a bolus adjustment in order to
reach this goal. A modest rise at the time of bolusing may necessitate enough extra insulin to offset a 20-30 mg/dl (1-1.5 mmol) rise. A sharp rise could include enough extra insulin to offset a 40-60 mg/dl (2-3 mmol) rise. Likewise, a decline (modest or sharp) may necessitate a corresponding bolus reduction.

**Who benefits most:** Those with undue glucose variability, which is believed to increase adverse outcomes. *(53,54,55)*

Use the Numbers

Despite product label warnings to the contrary, users of CGM systems often use the displayed glucose values for decision-making purposes *without* confirmatory fingersticks. There are possible advantages to this practice: For those who normally perform fingersticks infrequently, it at least provides a reasonable basis for food, exercise and insulin dose decision-making. For those who test their blood glucose excessively, it allows for a reduction in the frequency of the costly and painful fingerstick procedures.

However, CGM users should be guided appropriately regarding the direct application of CGM readings. The “trustworthiness” of the readings should be taken into account. Specifically, CGM readings should only be used for making management decisions if:

1. The system has been generating data for at least 12 hours. During the first 12 hours of use, accuracy is more suspect than after the sensor has been in place for a period of time.
2. Calibrations have been performed sufficiently, and the last couple of calibration (fingerstick) values have matched the sensor values closely, with less than 15% discrepancies.
3. The current glucose is not rising or dropping rapidly, since CGM systems lag behind actual blood glucose values (the concept of “lag time” will be discussed in the next section).
4. The CGM has not generated any error messages or displayed data gaps for the past couple of hours.

**Who benefits most:** Those who currently check blood glucose more than ten times daily; those with a pronounced dislike for fingerstick testing.

Retrospective Review of Data

Professional or diagnostic CGM devices are owned by health care professionals and “borrowed” by patients to be worn for approximately 3 successive days for data collection. With professional CGM, patients are unaware of the glucose data generated. This means that minimal patient training is required, although both patient and provider benefit from the advantages of continuous data analysis. *(22,56,57)*

Historical glucose information can be evaluated two different ways: by visualizing recent trend data on the real-time CGM display itself, or by downloading the CGM (real-time or professional version) to computer-based programs. The computer programs have the ability to generate a variety of graphs and statistics, including the glucose average, standard deviation, percent of time spent above, below and within target range, number of excursions above and below target range, detailed daily reports, and
modal day reports which superimpose multiple days of trend data onto a single chart. The modal day report, in particular, can reveal glucose patterns related to meals, exercise, and insulin dosing decisions.

Prior to evaluating historical data, it is important to ensure that the information is reasonably accurate. Were sufficient calibrations performed, and did the calibrations match the concurrent sensor values well? Was the system free of signal transmission problems? And were the time and date set correctly on the CGM receiver?

Whether viewed on the computer or on the CGM display itself, historical information can provide insight in a number of key areas, even in Type II patients not using insulin. (58,59)

Postprandial Control

Viewing CGM data after meals, especially for the first one to two hours, can reveal both the timing and magnitude of postprandial spikes. Users and clinicians can evaluate the postprandial effects of different food types for meal planning purposes. Optimal timing of mealtime boluses, the need for mealtime rapid-acting insulin, choice of insulin secretagogue, and decisions to use pramlintide or incretins can also be evaluated. For patients with gastroparesis, patterns can strategies implemented related to bolus insulin timing and, in the case of pump use, application of extended bolus features.

Examples of postprandial “spikes”

**Who benefits most:** Those having difficulty achieving an A1c below 7%; those whose A1c does not match fingerstick averages, those who are symptomatic with rapid rise & fall of blood glucose.

Bolus Effectiveness

Analyzing the glucose levels three to four hours post-bolus provides useful insight regarding bolus dosing. Glucose levels that are consistently above or below target at this time indicate a need to adjust meal doses (insulin-to-carbohydrate ratios) or correction doses (insulin sensitivity).

**Who benefits most:** Those taking rapid-acting insulin at mealtimes

Dosage Adjustments for Patients Taking Incretins
For those using an incretin to regulate glucose levels, a review of post-meal patterns should indicate whether a sufficient dose is being taken, as glucose levels should remain fairly stable post-meal. For those taking rapid-acting insulin along with an incretin, insulin dose timing can be evaluated. A glucose drop soon after eating, followed by a rise over the next couple of hours, indicates a need to either delay or extend delivery of the mealtime insulin.

**Who benefits most:** Those starting to take an incretin mimetic.

**Exercise Adjustments**

Following exercise sessions, a review of short-term glucose patterns can guide the user regarding subsequent insulin and snack adjustments. Analysis of long-term patterns can also reveal the extent to which certain forms of exercise contribute to a delayed fall in blood glucose.

**Who benefits most:** Athletes and anyone who exercises on a regular basis.

**Stress and Illness Management**

Many people with diabetes fail to realize the impact physical and emotional stress can have on glucose control. In some instances, stress will cause an abrupt or prolonged glucose rise. At other times, it can make glucose levels drop. Understanding the impact of various forms of stress can prepare the user to make intelligent adjustments. During “sick days,” CGM can alert the user of extreme glucose levels, thus providing an early warning system for the prevention of both ketoacidosis and severe hypoglycemia.

**Who benefits most:** Those with unpredictable / erratic glucose responses to stress.

**Basal Insulin Fine-Tuning**

The long-term trend graphs on the CGM display (or downloaded reports) can play a vital role in the regulation of basal insulin, particularly overnight. Whether insulin is taken by way of injections or a pump, the basal insulin should hold the glucose level steady in the absence of food, exercise, rapid-acting insulin and major stress. Observe the CGM’s trend graph starting approximately 4 hours after a meal is eaten and rapid-acting insulin is taken. If the glucose level holds steady from this point onward, the basal insulin during that time is set correctly. If the glucose is rising or falling, the basal insulin probably needs adjustment.

In the example below taken from an insulin pump user, with a meal eaten (and bolus given) at 11:30am, the glucose level begins to take a downturn at around 4pm. Given that no exercise was performed in the afternoon, this indicates that the basal insulin may be set too high in the late afternoon.
In the next example, taken from a patient using an injectable basal insulin, the glucose level is rising from 2am until 8am, a pattern typical of the ‘dawn’ effect. (61) This may indicate the need to increase the basal insulin dose.

Who benefits most: Those who use insulin pumps

Action Curve Determination

CGM trend graphs can be used to determine the action curve for an individual’s rapid-acting insulin. That is, how long it takes for bolus insulin to finish working. This is valuable in determining “insulin-on-board” or “active/unused insulin” in mealtime dosage calculations. Action curves can vary from person to person, but typically fall in the range of three to five hours. Setting the duration of insulin action for a longer-than-actual time period will result in overestimation of insulin on board and underdosing (increasing the risk of hyperglycemia). Setting the duration too short will result in underestimation of insulin-on-board and over-dosing (and increased risk of hypoglycemia). To determine the action curve, check to see how long it takes the glucose to stop dropping after giving a
bolus dose of rapid-acting insulin. Once the line “flattens out”, the insulin has effectively run its course (see example below).

Who benefits most: Those who take frequent injections (or boluses) of rapid-acting insulin

Detection of Asymptomatic Lows and “Rebounds”

Post-hoc evaluation of CGM data can uncover hidden causes of hyperglycemia. Undetected hypoglycemia, particularly during sleep, is common for insulin-treated patients. Nocturnal hypoglycemia often produces fasting hyperglycemia secondary to counterregulatory hormone secretion. A review of overnight CGM patterns can reveal whether morning highs are the product of overnight lows. Of course, the adjustment to remedy fasting highs will depend on the cause.

In addition, symptomatic lows may produce a rebound high glucose, particularly if the patient overtreats with excessive amounts of carbohydrate. Referral for diabetes/nutrition education may be in order if hypoglycemia is usually followed by hyperglycemia.

Who benefits most: Those with difficulty controlling fasting glycemia

IV. Dealing with the Downsides

CGM systems are far from ideal. Their accuracy is still considered inferior to fingerstick testing. The alarms and maintenance requirements can be an annoyance. They can be uncomfortable, and the cost can be prohibitive. Part of the clinician’s job is to help patients realize the benefits of CGM while preparing them to deal effectively with the system drawbacks.

Accuracy Issues:

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Even though CGM systems use similar technology to measure glucose levels as most fingerstick meters, the accuracy remains somewhat inferior. Despite the fact that sensor accuracy improves with each new system generation, CGM-generated glucose values still vary from simultaneous fingersticks by an average of 10-20%. (22)

Accuracy issues are due in part to lag time – a 10-15 minute gap caused by the measurement of interstitial fluid rather than direct blood and the systems’ averaging data over a few minutes – as well as the creation of encapsulation tissue around the sensor itself. (62-66) Lag time in particular must be taken into account when setting alarm limits. When glucose is falling, the sensor will tend to read higher than the actual blood glucose. Low alerts should be set somewhat higher than the patient’s actual threshold for hypoglycemia.

To prevent patients from becoming discouraged by accuracy issues, it is important to establish realistic expectations prior to acquiring a CGM. Explain to patients that CGM-generated glucose values are merely estimates. The true value of CGM comes from the high/low alerts, trending information, and data analysis that can be performed after wearing the sensor over time.

Calibration plays an integral role in achieving optimal system accuracy. All data generated by the CGM is based on user-entered calibration values. Emphasize the importance of accurate, timely calibration:

- It is best to calibrate when glucose levels are relatively stable to avoid discrepancies related to lag time
- Calibrate at the times and frequency recommended by the device manufacturer
- Ensure that the fingerstick readings used for calibration are accurate: test on the finger (rather than an alternate site), clean the finger before testing, apply a sufficient drop of blood to the test strip, make sure the meter is coded properly (on meters that require coding)
- Enter the fingerstick value immediately after performing the test

Remind patients to not use medications that are known to hinder the accuracy of certain CGM systems. When using predictive alerts, set them for the shortest time interval possible. The longer the time between the alarm and the perceived high/low value, the greater the chances that the glucose trend line will deviate from its current path. Also, encourage users to be patient. Most users find that sensor accuracy tends to improve with age. Most major inaccuracies occur during the first day or two of use.

“Annoyances”:

CGM systems can produce many different alerts: high and low glucose alarms, predictive high and low glucose alarms, upward and downward rate of change alarms, and general system alarms (battery issues, sensor change reminders, and calibration reminders). While useful from a diabetes management standpoint, the frequency of alarms can become disruptive to the user, especially during the first few weeks of use.

To minimize the frequency of alarms, set the high and low glucose alerts at levels that are well above and below actual target glucose ranges, particularly during the first several weeks of system utilization. These levels can gradually be brought towards desired target ranges with improvements in control and experience using the system. It may also be best to leave the other alarms (predictive alarms, rate of
change alarms) in the off mode until the user is comfortable with the system’s basic features. Calibration reminder alarms can be avoided entirely by calibrating on a regular schedule, including before bedtime in order to avoid reminders while sleeping.

Skipped data can get in the way of daily use and be another source of frustration for the user. To minimize data loss, the user should wear the receiver/display on the same side of their body as the sensor. This reduces “water interference” caused by the body itself (radio signals from the transmitters do not travel through water). Make sure the transmitter is properly charged and seated/attached to the sensor. Report any repeated problems to the manufacturer; it is possible that the transmitter or receiver is defective and needs to be replaced.

Maintenance:

Having to change and re-start a sensor that is working well is costly and a hassle. It is generally not necessary to change sensors when their approved usage life has expired. Experience has shown that CGM sensors can often be worn for two or more “life cycles”. This rarely causes a downgrade in system accuracy, nor does it cause relevant site irritation. However, additional tape may be needed to prevent accidental detachment.

Re-charging transmitters and/or receivers is best performed during sensor changes (during a warm-up period), or when the user is still and stationary (while watching TV, at the computer, or sleeping).

Discomfort:

Although the sensors are composed of a flexible material, the introducer needle used to insert them can cause momentary pain. Use of the mechanical insertion devices that accompany the sensors helps to ensure proper/rapid insertion and minimal discomfort. Insertion at the appropriate angle (not too sharp or close to the skin surface) also reduces pain over the life of the sensor. Likewise, choosing an insertion site that has adequate subcutaneous fat (not near bone, scar tissue or muscle) can improve comfort considerably.

Cost Concerns:

The out-of-pocket cost for a CGM system and ongoing sensors may be beyond the reach of many patients. However, health insurance coverage is improving all the time. Many private and public health plans offer some level of coverage. CGM is usually considered “durable medical equipment” and is subject to the same deductibles and co-pays as other types of DME. Every CGM company has a team of specialists dedicated to helping customers obtain maximum coverage.

Those with Type-1 diabetes often qualify for coverage if the following criteria are met:

- A history of hypoglycemia, documented in the physician’s chart/records
- Presence of hypoglycemia unawareness
- Erratic blood glucose levels
- Suboptimal HbA1c
• Frequent blood glucose monitoring
• Completion of diabetes self-management education

In some cases, individuals with Type-2 diabetes can obtain coverage if many of these same conditions exist.

Most health plans will only cover CGM if it is prescribed by an endocrinologist. Letters from both the patient and physician, supporting the need for CGM, are often helpful in securing coverage.

There are several online resources that you and your patients can access:

The Juvenile Diabetes Research Foundation details the steps for obtaining case-by-case coverage for CGM at its website: http://www.jdrf.org/index.cfm?page_id=106514

CGM coverage policies for select health plans are listed at: http://www.jdrf.org/index.cfm?page_id=111281

Excellent sample letters for establishing medical need can be found at: http://www.diabeteshealth.com/read/2009/02/27/6096/sample-request-for-cgm-insurance-coverage/

For Additional resources for CGM Insurance Coverage, visit the CGM Anti-Denial Campaign Website: http://cgm-antidenial.ning.com

A comprehensive list of published articles supporting CGM use can be found at: http://www.theCGMresourcecenter.com

V. Summary / Key Points

There is a clear need for better tools to enable patients and clinicians to improve glycemic control. Research suggests that consistent use of CGM can reduce HbA1c levels, glycemic variability and the frequency, duration and magnitude of hypoglycemic events. Improved pregnancy outcomes have also been associated with CGM use.

Use of both real-time (patient use/interpretation) and professional (blinded use with clinician review of data) can benefit certain subsets of the diabetes population, particularly:

• Anyone with type-1 diabetes looking to improve their A1c without undue hypoglycemia
• Those with a history of severe hypoglycemia and hypoglycemia unawareness
• Athletes utilizing intensive insulin therapy
• Individuals transitioning to new forms of diabetes therapy
• Patients who currently check blood glucose very frequently or very infrequently
• Women with type-1 diabetes considering pregnancy
• People with type-2 diabetes who experience considerable glucose variability

There is considerable value to real-time CGM, even without taking specific glucose readings into account. High/low alerts can keep patients from veering into dangerous levels of glycemia, as long as the user responds to the alerts appropriately. Directional trends offer the opportunity to predict glucose levels in the short-term, which has important implications for mealtime dosing decisions as well as therapy adjustments prior to key events such as tests, driving, sports participation, and high-risk work or recreational activities.
Retrospective analysis of CGM data offers both system users and their healthcare providers an opportunity to evaluate the overall management program, including a detailed analysis of:

- Postprandial glucose levels
- Basal insulin dosing
- Bolus insulin dosing
- The effectiveness of incretins
- Exercise/sports responses
- Patterns of hypoglycemia
- Insulin action curves
- The impact of stress and illness

CGM is not without its drawbacks. System inaccuracy, disruptive alarms, discomfort, routine maintenance, and out-of-pocket costs can deter long-term use of CGM. To help patients benefit most from this technology while minimizing the drawbacks, the healthcare team should be prepared to provide coaching and education before and during CGM initialization.

Bibliography


49. John Mastrototaro, Ph.D., John B. Welsh, M.D., Ph.D., and Scott Lee, M.D., Practical Considerations in the Use of Real-Time Continuous Glucose Monitoring Alerts *Journal of Diabetes Science and Technology* 2010, 4: 733-9


54. Colette & Monnier. Glycemic variability: should we and can we prevent it?, *Horm Metab Res* 2007;39:683-6

55. Kilpatrick et al. for debate. Glucose variability and Diabetes Complication Risks: we need to know the answer, *Diabet. Med.* 2010;27;868–871,


59. Rodbard D., Interpretation of Continuous Glucose monitoring data: Glycemic Variability and Quality of Glycemic Control, *Diabetes Tech and Therapeutics,* 2000;11. S-55,

60. Michael Riddell, Ph.D.1 and Bruce A. Perkins, M.D., M.P.H., FRCP(C)Exercise and Glucose Metabolism in Persons with Diabetes Mellitus:
61. Mary F. Carroll, MD, and David S. Schade, MD, THE DAWN PHENOMENON REVISED: IMPLICATIONS FOR DIABETES THERAPY
ENDOCRINE PRACTICE 2005; 11: 55-64.


