Continuous Glucose Monitoring Practical Applications and How It Is Changing Clinical Practice

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8/3/19
Objectives

- Review current commercially available CGM devices in the US
- Review current CGM use in clinical practice
- Review clinical studies that support broader use of CGM as Standard of Care
- Discuss therapeutic use of new DEXCOM CGM
YOU CAN DO IT!!

You can do it without fingersticks.

You can do it without fingersticks.

Fingersticks are required for treatment decisions when you see Glucose Gague symbol when symptoms don't match system readings, when you suspect readings may be inaccurate, or when you experience symptoms that may be due to high or low blood glucose.

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FreeStyle Libre 14 day

You can do it without fingersticks.
Real-Time CGM (rtCGM)

- Sensor data transmitted continuously to a receiver or display device, which allows for alerts and alarms to be provided to the wearer without any action.

Intermittently Scanned CGM (isCGM)

- Sensor data not transmitted continuously.
- Results are available only when the sensor is scanned with a reading device; no alerts without scanning.
- Full 24-h data can be captured and downloaded if the sensor is scanned at least every 8 hours.
Real-time CGM is a useful tool to lower AIC in adults with TID who are not meeting glycemic targets (A)

Real-time CGM may be a useful tool in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes (B)

Real-time CGM should be used daily for maximal benefit (A)

Real-time CGM may be used to improve AIC levels and neonatal outcomes in pregnant women with TID (B)

Real-time CGM should be considered in children & adolescents with TID to improve glucose control and reduce the risk of hypoglycemia (B)
Current State of Diabetes Management

8.4
Average A1C% level of type 1 patients¹

69%
Insulin using patients above ADA A1C target of 7%²

70%
Patients not taking their insulin as prescribed³

The barriers to good glycemic control are wide-ranging and far-reaching, contributing not only to long-term complications but also hindering a patient’s day-to-day quality of life.⁴,⁵

Intermittent Monitoring Is Not Enough

![Graph showing Glucose levels over time with healthy glucose range marked.]

*Self-Monitoring of Blood Glucose (SMBG)*
Intermittent Monitoring Is Not Enough

![Graph showing glucose levels over time with a highlighted healthy glucose range.](image-url)
Intermittent Monitoring Is Not Enough

- **CGM**
- **Over 4 hours above 210 before SMBG**
- **Above 140 for 13.5 hours**
- **Healthy Glucose Range**
- **Severe Hypoglycemia for 1 hour**

*Self-Monitoring of Blood Glucose (SMBG)*
CGM Use Has Increased but the Majority of T1D Do Not Use

T1D Exchange Clinic Registry; data through March 31, 2018
T1D Exchange Shows Improved A1C with CGM

- A1C level similar in CGM users regardless of insulin delivery method
Current Commercially Available Personal CGM’s in US

- Dexcom G5
- Dexcom G6
- Abbott FreeStyle Libre
- Medtronic Guardian Connect
- Senseonics
Current Commercially Available CGM Integrated Systems in the US – Personal Use

- Tandem t:slim X2 with Basal IQ
- Medtronic 630G
- Medtronic 670G
CGM – A New Standard of Care

Consensus statements from endocrine experts have now become more specific on the demonstrated benefits of CGM

American Diabetes Association 2019¹
- RT-CGM used in conjunction with intensive insulin therapy is a useful tool to lower A1c in adults with type 1 diabetes who are not meeting glycemic targets

American Association of Clinical Endocrinologists (AACE) 2016²
- CGM usage improves glycemic control, reduces hypoglycemia, and may reduce overall diabetes management costs
- CGM should be used in all patients who have severe hypoglycemia or hypoglycemia unawareness

Endocrine Society 2016³
- Recommends CGM for adults with type 1 diabetes and
- Recommends short-term, intermittent CGM for adults with type 2 diabetes and A1c ≥7%
- 2016 recommendations addressed use in adults only. The 2011 guidelines recommended CGM for children and adolescents with T1D and A1c>7%⁴

Advanced Technologies & Treatments for Diabetes (ATTD) 2017⁵
- CGM should be considered in conjunction with A1c to assess glycemic status and adjust therapy in all patients with type 1 diabetes and in patients with type 2 diabetes treated with intensive insulin therapy who are not achieving glucose targets

Considerations for Patient Selection

rtCGM (Dexcom G5 & G6)

All IIT patients
At increased risk for hypoglycemia:
  • Those with hypoglycemia awareness & unawareness
  • Frequent nocturnal hypoglycemia
  • Frequent severe hypoglycemia
  • Significant glycemic variability

Hypoglycemia fear
Could benefit from remote monitoring
Desire tighter glucose control
High A1C
Physically active and/or busy lifestyle
Cannot achieve adequate glucose control with isCGM
Considerations for Patient Selection

**rtCGM (Dexcom G5 & G6)**

- All IIT patients
- At increased risk for hypoglycemia:
  - Those with hypoglycemia awareness & unawareness
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  - Frequent severe hypoglycemia
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**Hypoglycemia fear**

- Could benefit from remote monitoring
- Desire tighter glucose control
- High A1C
- Physically active and/or busy lifestyle
- Cannot achieve adequate glucose control with isCGM

**isCGM (Libre)**

- Newly diagnosed T2D
  - Not treated with insulin
  - Are under good control and want to avoid fingersticks
  - Does not want/need alerts
  - Motivated to scan their device
  - Low/no risk of hypoglycemia
## Product Overview

<table>
<thead>
<tr>
<th>Features</th>
<th>Dexcom G6 Mobile CGM</th>
<th>Abbott FreeStyle Libre isCGM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audible alerts</td>
<td>Yes</td>
<td>Visual alerts (must scan to view)</td>
</tr>
<tr>
<td>Built-in low safety alarm</td>
<td>None required</td>
<td>No alarm</td>
</tr>
<tr>
<td>Streaming real-time data</td>
<td>2 hours</td>
<td>Factory calibration</td>
</tr>
<tr>
<td>Remote monitoring</td>
<td>Yes</td>
<td>Data available only with user intervention</td>
</tr>
<tr>
<td>Yes - with Tandem x2</td>
<td>No</td>
<td>1 hour</td>
</tr>
<tr>
<td>10 days</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Yes – as young as 2 years old</td>
<td>14 days</td>
<td>No – 18 years and older only</td>
</tr>
<tr>
<td>No contraindication</td>
<td></td>
<td>Not contraindicated</td>
</tr>
<tr>
<td>Compatible with device wearables</td>
<td>Yes</td>
<td>Not compatible</td>
</tr>
<tr>
<td>Device compatibility</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Dosing without Fingersticks Confirmation Across All Glucose Ranges</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Product Overview

<table>
<thead>
<tr>
<th>Feature</th>
<th>Dexcom G6 Mobile CGM</th>
<th>Medtronic 670G rtCGM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audible alerts</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Built-in low safety alarm</td>
<td>None required</td>
<td>Audible Alerts</td>
</tr>
<tr>
<td>Streaming real-time data</td>
<td>2 hours</td>
<td>Streaming real-time data</td>
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<tr>
<td>Warm-up period</td>
<td>Yes</td>
<td>2 hours</td>
</tr>
<tr>
<td>Remote monitoring</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Pump integration</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Length of sensor wear</td>
<td>7 days</td>
<td>Length of sensor wear</td>
</tr>
<tr>
<td>Pediatric approval</td>
<td>Yes - as young as 2 years old</td>
<td>Pediatric approval</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>No contraindication</td>
<td>Acetaminophen</td>
</tr>
<tr>
<td>Device compatibility</td>
<td>Compatible with device wearables</td>
<td>Device compatibility</td>
</tr>
<tr>
<td>Dosing without Fingersticks Confirmation Across All Glucose Ranges</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>FreeStyle Libre 14-Day¹</td>
<td>Guardian Connect²</td>
</tr>
<tr>
<td>-------------------------</td>
<td>------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td><strong>If symptoms or expectations do not match sensor glucose value</strong></td>
<td>During the first 12 hours of readings</td>
<td>Before making treatment decisions, such as dosing insulin before a meal or taking carbs to treat a low</td>
</tr>
<tr>
<td><strong>Symptoms of hypoglycemia</strong></td>
<td>If you have hypoglycemic unawareness (lack of symptoms)</td>
<td>Symptoms of hypoglycemia</td>
</tr>
<tr>
<td><strong>Symptoms of hyperglycemia</strong></td>
<td>Within 2 hours after connecting a new sensor</td>
<td>Symptoms of hyperglycemia</td>
</tr>
<tr>
<td><strong>When glucose is rapidly falling</strong></td>
<td>Within 6 hours after first calibration</td>
<td></td>
</tr>
<tr>
<td><strong>When glucose is rapidly rising</strong></td>
<td>Within 12 hours of second calibration and at least every 12 hours thereafter (3-4x daily recommended for accuracy)</td>
<td>Twice per day after initialization phase, spaced 10-14 hours apart</td>
</tr>
<tr>
<td><strong>Impending hypoglycemia</strong></td>
<td>Hypoglycemia</td>
<td></td>
</tr>
<tr>
<td><strong>Hypoglycemia</strong></td>
<td>When blood glucose is changing rapidly</td>
<td></td>
</tr>
<tr>
<td><strong>Anytime the Check BG icon appears</strong></td>
<td>During illness or times of stress</td>
<td></td>
</tr>
<tr>
<td>If you will be driving a car or operating machinery</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Dexcom Provides Audible Alerts Without User Intervention

Only Dexcom offers active monitoring with audible alerts

Hypoglycemia occurring during sleep\(^1\)

55% 43%

Hypo Episodes <70 mg/dL Severe Hypo Episodes <55 mg/dL

Dexcom CGM System with alerts can help increase time in target range

76

Median increase of 76 minutes/day was observed during the DlaMonD study\(^2\)

Commercial Available CGM Systems Accuracy During the Critical Low Glucose Range (40-60mg/dL)

<table>
<thead>
<tr>
<th>Sensor System</th>
<th>Accuracy Matched to Reference Value (YSI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexcom G6</td>
<td>68%</td>
</tr>
<tr>
<td>Abbott Libre 14-day</td>
<td>25%</td>
</tr>
<tr>
<td>Medtronic 670G</td>
<td>31%</td>
</tr>
</tbody>
</table>

## Accuracy of Commercially Available CGM Systems

<table>
<thead>
<tr>
<th></th>
<th>G6 No Cal&lt;sup&gt;4&lt;/sup&gt;</th>
<th>Guardian Connect&lt;sup&gt;1,2&lt;/sup&gt;</th>
<th>FreeStyle Libre&lt;sup&gt;3&lt;/sup&gt;</th>
<th>Senseonics&lt;sup&gt;5&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall MARD%</td>
<td>9.0</td>
<td>10.6&lt;sup&gt;1&lt;/sup&gt;</td>
<td>9.1 arm&lt;sup&gt;1&lt;/sup&gt;</td>
<td>10.1</td>
</tr>
<tr>
<td>Overall %20/20</td>
<td>94</td>
<td>86&lt;sup&gt;1&lt;/sup&gt;</td>
<td>90 arm&lt;sup&gt;2&lt;/sup&gt;</td>
<td>90</td>
</tr>
<tr>
<td>Day 1 MARD%</td>
<td>9.3</td>
<td>?</td>
<td>10.8 arm&lt;sup&gt;2&lt;/sup&gt;</td>
<td>11.1</td>
</tr>
<tr>
<td>Day 1 %20/20</td>
<td>92</td>
<td>77&lt;sup&gt;1&lt;/sup&gt;</td>
<td>84&lt;sup&gt;1&lt;/sup&gt;</td>
<td>86.3</td>
</tr>
<tr>
<td>Hypoglycemia 40-60mg/dL (concurrency of CGM readings with YSI values)</td>
<td>67.8%</td>
<td>30.7%&lt;sup&gt;1&lt;/sup&gt;</td>
<td>41.9% arm&lt;sup&gt;1&lt;/sup&gt;</td>
<td>24.7%</td>
</tr>
</tbody>
</table>

Accuracy

- MARD – Mean Absolute Relative Difference

- MARD is the result of a mathematical calculation that measures the average disparity between the sensor and the reference measurement. The lower the MARD, the more accurate the device is considered.

- Calculate MARD
  - Difference of Capillary BG (blood glucose) vs Difference CGM BG
  - Average of |Difference| / mean of cap. BG x 100%

Figure 2. Box plots for the MARD on successive study days. Displayed are mean (diamonds), median (horizontal lines within boxes), 25th and 75th percentiles (lower and upper edge of the boxes), and minimum and maximum values (asterisks).
Dexcom System MARD* by Generation

Accuracy

G6 No Cal (Pre-Pivotal)
# Dexcom G6 Accuracy: Safe For Diabetes Treatment Decisions in Pediatrics

<table>
<thead>
<tr>
<th>Population</th>
<th>Participants (N)</th>
<th>Matched Pairs (N)</th>
<th>%20/20 (%)</th>
<th>MARD (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>62</td>
<td>3,532</td>
<td>93.9</td>
<td>9.0</td>
</tr>
<tr>
<td>Adults (ages 18+)</td>
<td>25</td>
<td>2,145</td>
<td>92.5</td>
<td>9.8</td>
</tr>
<tr>
<td>Children (ages 6-17)</td>
<td>37</td>
<td>1,387</td>
<td><strong>96.2</strong></td>
<td><strong>7.7</strong></td>
</tr>
</tbody>
</table>

Accuracy in pediatric participants was similar whether they wore the sensor on their abdomen (%20/20=97.6%) or their upper buttocks (%20/20=94.2%)
Clinical Studies and Outcomes
Personal CGM Benefits Diverse Users Proven by Outcome Studies

- JDRF
- JDRF well-controlled
- EU Hypo reduction study
- STAR 3
- SWITCH Study

Predominantly Pump Users

- Gold
- Diamond T1D cohort
- Diamond T2D cohort
- COMISAIR

MDI
T1 DM
DlaMonD Phase 1 - Methodology and Study Design

- Six-month randomized control trial
- Adult subjects (≥25 y) randomized to MDI+CGM or MDI+SMBG
- Baseline A1C = 8.6%
- All subjects used G4 PLATINUM (with software 505)
- Subjects were instructed to use CGM according to adjunctive labeling indication
- Study design approximated usual clinical practice over 6 months
  - 5 visits
  - 2 phone calls
Dexcom CGM Lower A1c and Improved Overall Quality of Glucose Control with MDI Patients

CGM Added to Type 1 MDI Patients Lowered A1C by 1.0% Within 6 Months

<table>
<thead>
<tr>
<th>Baseline A1C = 8.6%</th>
<th>CGM Group (n=105)</th>
<th>Control Group (n=53)</th>
<th>Difference</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in A1C from baseline</td>
<td>-1.0%</td>
<td>-0.4%</td>
<td>-0.6%</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mean adjusted difference, % (99%CI)</td>
<td>(0.8-0.3)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

| A1C Reduction ≥1.0% or A1C <7.0% | 52% | 21% | 31% | <.001 |

| Time in Target (70-180mg/dL) | 77 min/day | no change | <.005 |
| Hypoglycemia (<70mg/dL) | 22 min/day | 8 min/day | <.002 |
| Hyperglycemia (>180mg/dL) | 49 min/day | 15 min/day | <.001 |

| Glucose variability | 38 | 42 | -4 | <.001 |
| coefficient of variation, mean (SD), % | (6) | (7) | (-6 to -2) |
How Does DlaMonD Outcomes Effect My Clinical Practice?

- **Age (A1C)**
  - 25-45 years = 0.9%
  - ≥ 60 years = 1.0%

- **Diabetes Numeracy Score (A1C)**
  - ≤60% = 1.1%
  - >60% = 0.9%

- **Education (A1C)**
  - ≤ Bachelor’s degree = 1.0%
  - ≥ Bachelor’s degree = 1.0%

- **A1C ≥8.5%**
  - Average A1C reduction = 1.3%

93% of patients wore CGM ≥6 days per week

Patients decreased SMBG ~1.5 finger sticks/day
Continued Evidence A1C Reduction Is Considerable with MDI + CGM, But Dependent on Continuous Use

Baseline A1C Reduction with CGM + MDI: 0.8%

Between Group A1C Reduction with SMBG + MDI and CGM + MDI: 0.4%

More severe hypoglycemia in SMBG + MDI group (12 events vs. 1 event)

88% of time CGM worn throughout the study
GOLD Study Demonstrates Considerable Reduction in Time Spent Hypoglycemic with Continuous Use of CGM

Glucose < 70 mg/dL

- Conventional therapy
- Washout period
- CGM therapy

Mean +/- SE percentage

Month
Incremental Benefit of Adding an Insulin Pump for Patients Already Using CGM

**Phase 1**
168 enrolled and 158 randomized

- **105 to CGM + MDI**
- **53 to Control (MDI + BGM)**

24 Week Phase 1 RCT; results in JAMA 2017; 31(4): 371-378.

- **A1C=8.6%**
- **A1C=7.6%**

**Phase 2**
102 from CGM + MDI group eligible; 75 enrolled

- **38 MDI**
- **37 CSII**

- Omnipod pump used
- Both groups continued with CGM
- Dexcom G4 with Software 505
- Primary endpoint = Time in Target
- 6 month duration

A1C=???
DiaMonD Phase 2 – The Addition of CSII Improves Time in Range, Increases Time in Hypoglycemia, No Further Reduction in A1c

<table>
<thead>
<tr>
<th>Step</th>
<th>A1C (%)</th>
<th>CGM</th>
<th>A1C (%)</th>
<th>CGM+CSII</th>
<th>A1C (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDI (no technology)</td>
<td>8.6</td>
<td></td>
<td>7.6</td>
<td></td>
<td>7.9</td>
</tr>
<tr>
<td>MDI+CGM (6 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDI+CGM (6 months) then add CSII (next 6 months)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Time in Target (70-180 mg/dL)**
- Increased by 83 min/day (95% CI 17 to 149) \( p = 0.01 \)

**Hypoglycemia (<70 mg/dL)**
- Increased by 15 min/day \( p = 0.0001 \)

**Hyperglycemia (>180 mg/dL)**
- Decreased by 47 min/day \( p = 0.007 \)

- Daily insulin dose decreased with CSII, yet increase in boluses/day
- CGM adherence was excellent at 96% wear time of ≥6 days/week throughout study
- Adverse events:
  - MDI group – 1 severe hypoglycemic episode
  - CSII group – 1 DKA episode and 1 hospitalization due to hyperglycemia without DKA

Beck RW et al., Lancet Diabetes Endocrinol, 2017
COMISAIR Study Demonstrated Most Improved A1c ONLY with the Addition of CGM Regardless of Insulin Delivery Method

65 T1D patients were followed up for a year (3 groups): 27 patients with Sensor-Augmented Insulin Regimens (15 on CSII + RT-CGM & 12 on MDI + RT-CGM); 20 patients on CSII therapy alone; 18 subjects on MDI alone
Irrespective of Insulin Delivery - A1C Reductions Greater with CGM

Linear mixed model adjusted for age at diagnosis and gender

[Reference: Multicoll (et al.), Diabetes Technology & Therapeutics 2019, Jan. 23(1)]
Irrespective of Insulin Delivery - A1C Reductions Greater with CGM

Linear mixed model adjusted for age at diagnosis and gender
Mullins C (et al.), Diabetes Technology & Therapeutics 2019 Jan; 23(1)
Early Initiation of CGM Associated with Improved Glucose Control & Fewer Diabetes-related Emergency Visits Over 2.5 Years

Outcomes adjusted for a higher rate of private insurance among the CGM groups. Results at 2.5 years demonstrated:

- **A1C 1.5%** (MDI+CGM vs MDI) with **P<0.0001**
- **A1C 1.0%** (MDI+CGM vs CSII) with **P<0.0001**

No statistically significant difference between MDI+CGM vs CSII+CGM

The number of diabetes-related ED visits were lower among early CGM users compared with non-CGM users:

- **9%** (CGM Users) vs **22%** (Non-CGM Users) with **P=0.003**

(As cited from: Mulinacci, G et al., Diabetes Technology & Therapeutics, 2019. Jan. 23(1))
Discussion and Conclusions

- Early initiation of CGM was effective in lowering and maintaining A1C for 2.5 years and was associated with reduced diabetes-related ED visits regardless of age at diagnosis.

- MDI+CGM users had better outcomes than CSII without CGM users indicating that CGM is an appropriate first technology to initiate early into a patients diabetes care plan.

- Research indicates that glycemic control may settle in to long-term patterns within the first 5 years after diabetes thus CGM may help to improve long-term glycemic control and reduce diabetes complications.
T2 DM
Proven A1c Reduction with the Use of Dexcom CGM with Type 2 IIT Patients

- DlaMonD T2D: Randomized Trial of 158 adult MDI users with type 2 diabetes
  Change in A1c(%) with rtCGM in IIT T2 Subjects

<table>
<thead>
<tr>
<th>Baseline A1c ≥7.5%</th>
<th>Baseline A1c ≥8.0%</th>
<th>Baseline A1c ≥8.5%</th>
<th>Baseline A1c ≥9.0%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>-0.5</td>
<td>-0.6</td>
<td>-0.7</td>
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<tr>
<td>-0.2</td>
<td>-0.9</td>
<td>-0.9</td>
<td>-0.7</td>
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<td>-1.1</td>
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<td>-0.6</td>
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<td>-0.8</td>
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<td>-1</td>
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<td>-1.2</td>
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<td>-1.4</td>
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<tr>
<td>-1.6</td>
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</table>

A1c Reduction Across A1c Stratification
- Usual Care Group
- CGM Group
93% of subjects were wearing CGM ≥6 days/week in month 6

Mean A1C decreased 0.8% in CGM Group and 0.3% compared to Control Group (P=0.005)

CGM increased time-in-range (70-180mg/dL) and reduced hyperglycemia (>180mg/dL)

Little hypoglycemia (<70mg/dL) in both groups

<table>
<thead>
<tr>
<th>Baseline A1C</th>
<th>Change in A1C From Baseline</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CGM Group</td>
<td>Usual Care Group</td>
</tr>
<tr>
<td>≥ 7.5% *</td>
<td>-0.9% (n=79)</td>
<td>-0.5% (n=79)</td>
</tr>
<tr>
<td>≥ 8.0% *</td>
<td>-0.9% (n=63)</td>
<td>-0.6% (n=57)</td>
</tr>
<tr>
<td>≥ 8.5% *</td>
<td>-1.1% (n=39)</td>
<td>-0.7% (n=39)</td>
</tr>
<tr>
<td>≥ 9.0%</td>
<td>-1.4% (n=17)</td>
<td>-0.7% (n=21)</td>
</tr>
</tbody>
</table>
"Seniors": T1 and T2 insulin taking

Mean HbA1c Change from Baseline, %

- 1.0%
- 0.5%
0.0

N=63
N=53

CGM
Usual care

≥ 60 yrs

-1.0%
-0.5%
P=.001

97% used CGM>6 days/wk
First – We Need to Know What the Arrows Mean

<table>
<thead>
<tr>
<th>Dexcom G6 Trend Arrows</th>
<th>Glucose Direction</th>
<th>Change in Glucose</th>
</tr>
</thead>
<tbody>
<tr>
<td>App</td>
<td>Increasing</td>
<td><strong>Glucose is rapidly rising</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Increasing &gt;3 mg/dL/min or &gt;90 mg/dL in 30 minutes</td>
</tr>
<tr>
<td></td>
<td>Increasing</td>
<td><strong>Glucose is rising</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Increasing 2-3 mg/dL/min or 60-90 mg/dL in 30 minutes</td>
</tr>
<tr>
<td></td>
<td>Increasing</td>
<td><strong>Glucose is slowly rising</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Increasing 1-2 mg/dL/min or 30-60 mg/dL in 30 minutes</td>
</tr>
<tr>
<td></td>
<td>Increasing or Decreasing</td>
<td><strong>Glucose is steady</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not increasing/decreasing &gt;1 mg/dL/min</td>
</tr>
<tr>
<td></td>
<td>Decreasing</td>
<td><strong>Glucose is slowly falling</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Decreasing 1-2 mg/dL/min or 30-60 mg/dL in 30 minutes</td>
</tr>
<tr>
<td></td>
<td>Decreasing</td>
<td><strong>Glucose is falling</strong></td>
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<td></td>
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<td>Decreasing &gt;3 mg/dL/min or &gt;90 mg/dL in 30 minutes</td>
</tr>
</tbody>
</table>
Dexcom History Timeline

- 1999: 1st Gen Implantable Sensor
- 2006: STS 3-Day
- 2007: SEVEN
- 2009: SEVEN Plus
- 2012: G4 PLATINUM
- 2015: G5 Mobile
- 2018: G6 No Cal
Four Steps For Sensor Insertion: Peel – Press – Push – Place

Clinical Study Results

- 100% of all subjects rated the new applicator system as “very easy” or “somewhat easy”
- 84% rated the system as “painless”
- 100% of all subjects rated the instructions for sensor insertion to be “somewhat or very easy”
BG Meters Often Do Not Meet Accuracy Standards

1035 subjects
3 clinical sites
BG measurements obtained by trained HCPs

18 of the most widely prescribed BG meters and strips were purchased from retail pharmacies

Only 1/3 of the BG meters tested consistently met accuracy standards

ISO 15197-2013 requires 95% of data pairs to be within 15mg/dL < 100 mg/dL and 15% for values ≥ 100 mg/dL
## Poor Testing Technique

Skin contaminants reduce meter accuracy 1 hour after peeling fruit

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Washed Hands</th>
<th>Exposed Finger (No Washing)</th>
<th>One Alcohol Wipe</th>
<th>Five Alcohol Wipes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peeling an Orange</td>
<td>98 mg/dL</td>
<td>171 mg/dL</td>
<td>118 mg/dl</td>
<td>119 mg/dl</td>
</tr>
<tr>
<td>Peeling a Grape</td>
<td>93 mg/dL</td>
<td>360 mg/dL</td>
<td>274 mg/dl</td>
<td>131 mg/dl</td>
</tr>
<tr>
<td>Peeling a Kiwi</td>
<td>90 mg/dl</td>
<td>183 mg/dl</td>
<td>144 mg/dl</td>
<td>106 mg/dl</td>
</tr>
</tbody>
</table>
CGM Reimbursement and Criteria
Personal Reimbursement for CGM

- 98% of commercial plans cover CGM for T1D
  - Noted issues with high deductibles
- Medicare covers for therapeutic CGM (currently on Dexcom G5)
  - All IIT patients
- 30+ states have Medicaid coverage
- Coverage with DOD and VA
- In many cases, stand alone CGM can be obtained as a pharmacy benefit
Medicaid Coverage for CGM
# CGM Reimbursement Is Not A Barrier to Prescribing and Patient Use

## 2018 Continuous Glucose Monitoring (CGM) Coding Reference

<table>
<thead>
<tr>
<th>Codes/Description</th>
<th>RVU¹ Non-Facility*</th>
<th>Medicare¹ Physician Fee Schedule</th>
<th>Medicare² Outpatient Diabetes Center</th>
<th>Private Payor³ (2017 Averages)</th>
<th>Who Can Bill?</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT 95249 (Personal CGM – Startup/Training)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording.  
Bill once during time patient owns device. | 1.56 | $56.15 | $35.96 | 2018 rates not yet published; consult local payer for coding/payment advice. | Qualified RN, PharmD/RPh, RD, CDE, MAT¹ |
| CPT 95250 (Professional CGM – startup/Training) | | | | | |
| Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; equipment provided by the physician or other qualified healthcare professional, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording.  
Do not bill more than 1x/month. | 4.35 | $156.58 | $106.61 APC 5012 | $905 | Qualified RN, PharmD/RPh, RD, CDE, MAT¹ |
| CPT 95251 (CGM Interpretation) | | | | | |
| Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, Interpretation and report.  
Do not bill more than 1x/month. | 1.02 | $56.72 | Paid under Physician Fee Schedule | $90 | MD, NP, PA, CNS |
| E/M 99251-99215 | | | | | |
| Established Patient Visit | 0.57-4.08 | $20.45-145.43 | $106.61 APC 5012 GD483 (Medicare Outpatient Clinic Visits) | $46-281 | MD, NP, PA, CNS |

¹ Non-Facility is defined as office space.
² These individuals may perform this service if within their scope of practice and billed by the supervising physician or hospital outpatient department.
³ 2018 Private Payor rates not yet published; consult local payer for coding/payment advice.
Equipments
Setting Up a Clinic Account

- Register clinic at clarity.Dexcom.com/professional
- Add staff accounts
- Add a patient
- Invite patients to share data
  - print or email invitation
  - patient authorizes data sharing
- View patient data at any time
Patient List

Collect CGM data history with the Patient List.
- Displays all patients entered into the clinic account.
- Clinic staff can be given access to this page.
- Upload receiver data directly to the patient’s account.
- Save, print or export reports.
- View all reports interactively for more detailed data.
- Invite patients to authorize to share their data.

Dexcom CGM app users data is uploaded automatically into the clinic account when:

1. Clinic has entered as a patient in this list.
2. Sharing is authorized by the patient.
Data From the Receiver

- Data on a receiver can be uploaded by the patient at home or by the clinic during visits.
- When uploaded, the Dexcom CGM data is stored on a secure Cloud server.
- Receivers can only store about 30 days worth of data.
- It is a good practice for users to upload their receivers at least every 30 days to save all their data indefinitely.
Clinicians can view continuous patient data once the patient accepts the CLARITY clinic sharing invitation – which they can do with the CLARITY app on their smartphone.

Dexcom CGM data from smartphones streams and is stored on a secure Cloud server. It is current minus the last 3 hours. Retrospective data is not intended for real time use.
The Overview report presents a summary of the most relevant clinical patterns:

- Focuses the discussion on areas contributing to hyper- and hypoglycemia.
- Provides data specific to the date range selected.
- Summarizes the quality of glucose control via metrics.
- Identifies daytime and nighttime patterns of highs and lows.

We found 2 patterns during this date range. The best day was 17 July 2018.

1. Verena had a pattern of nighttime highs
   Verena had a pattern of significant highs between 22:00 and 22:40.
   10 high events contributed to this pattern. None of the contributing events were rebound highs.

2. Verena had a pattern of daytime highs
   Verena had a pattern of significant highs between 19:30 and 20:00.
   5 high events contributed to this pattern. None of the contributing events were rebound highs.

3. Verena's best glucose day
   Verena's glucose data was in the target range about 75% of the day.
Dive deeper with a daily micro-view of patient control.

- Begins discussions of what, why, and how to address issues.
- Enhances patient education in diabetes management.
Trends is a holistic visual representation of patterns. It helps prioritize clinical issues based on discussions with the patient.

- Longer bars represent greater glycemic variability.
- Clinically significant hypoglycemia patterns are red - the most significant are bright red.
- Hyperglycemia patterns are yellow - the most significant are bright yellow.
- Outlier data is removed to help focus on patterns, the top 25% and bottom 15%.

A stepwise approach may help you identify patient challenges with hypo- and hyperglycemia.
The Overlay features all CGM data points to help patients visualize patterns and individual events.

- Identify patterns of patients with irregular schedules.
- Filter data by day, daytime or nighttime, highs and lows, rebounds, and sustained events.
Every glucose reading is displayed in this report. Talk in-depth with patients about individual days and isolated events.
All CLARITY reports can be saved or printed for easy reference during patient visits.

When printed, this one page summary contains all information for billing 95251* which is a CPT code covered by most insurance carriers.
For The Patients
Mobile Push Notifications – Example Time in Range

Your CGM glucose readings were In Range 61% of the time last week (8/27-9/2). That’s a +2% change from the week before.

Press for more
Mobile Push Notifications – Example Time in Range

Your CGM glucose readings were In Range 61% of the time last week (8/27-9/2). That’s a +2% change from the week before.

Time in Range

61%

In Range for the week of Aug. 27 - Sep 2, 2017

+2%
Change since last week

156 mg/dL
Average Blood Glucose

49 mg/dL
Standard Deviation

In Range Settings: Daytime (7am-10pm): 70-140 mg/dL, Nighttime (10pm-7am): 90-160 mg/dL
The Dexcom CLARITY app was designed for patients. With it, patients can:

1. Accept the Sharing Code provided by the clinic. Once linked, for patients using the Dexcom CGM app, uploads are automatic and continuous.
2. View CLARITY statistics from the last 48 hours to 90 days.
3. Receive weekly notifications of key statistics to help stay on track.
4. View, save, and email any or all CLARITY reports from the last 48 hours to 90 days.
Case Study

- 30 y/o female
- DM1, Age 15
- On Omnipod and Dexcom
- Basal Rates:
  - 12:00 am – 3:00 am .7
  - 3:00 am – 7:00 am .75
  - 7:00 am – 12:00 pm .8
- I:C ratio 1:10, CF 1:50
- A1C 7.5 at last visit
We found 1 pattern during this date range. The best day was January 5, 2019.

- Jenna had a pattern of nighttime highs
  Jenna had a pattern of significant highs between 11:35 PM and 1:10 AM. 8 high events contributed to this pattern. None of the contributing events were rebound highs.

- Jenna's best glucose day
  Jenna's glucose data was in the target range about 87% of the day.
- High after meals
- Overnight Highs
- High glycemic variability
- Reassess correction factor
- Review timing of bolus
- Review timing of insulin to correct
Select two date ranges to compare side-by-side.
Coming Soon: Share Data With Up to 10 People

Additional Updates to Follow Include:

Similar look to G6 app

Night mode

Landscape view
Coming Soon: Voice Assistant Reports Glucose Number and Trend

“Hey Siri – What is my glucose?”

“Your glucose is 110mg/dL and flat”
Dexcom G6 Will Continue to Lead with Extensive Interoperability to Give Our Patients Options for Wearability

*Direct to Watch Connection not available in US or EU. Feature under development.*
G6 Interoperability (iCGM) with Insulin Delivery Devices
Empowering User Choice

Newly approved t:slim X2 with Basal IQ Technology

Insulin Pumps
TANDEM DIABETES CARE

Insulin Patch Pumps
Insulet

Smart Insulin Pens
Lilly

Automated Insulin Delivery Systems

Typezero
Diabeloop
Beta Bionics
Imperial College London
University of Cambridge

Sigma
Next Focus Is Electronic Health Records: integrating Dexcom API + Clarity Reports
CLARITY CGM Data and Reports EHR Integration Design Concept
EHR Integration: Dexcom Clarity Reports, On-Demand

While logged into their EHR, the clinician can order a specific patient’s CLARITY report and it will be delivered directly into that patient’s record in less than a minute. No additional log-ins required.

Dexcom cloud API

Any clinic, Any EHR

Clarity PDF in EHR
Dexcom Future Professional Product – Dexcom G6 Pro

- New professional CGM product
- Blinded/Real Time
- No Fingersticks
- 10 day wear
- Disposable sensor and transmitter
The Future of Dexcom CGM Technology

- Real-Time CGM
- Factory Calibrated
- Extended Sensor Wear
- Fully Disposable
- Simple Application
- Significant Cost Reduction
Thank God He Stopped Talking !!!!!