Professional Continuous Glucose Monitoring Implementation Playbook
The AADE® AANP® Professional CGM Implementation Playbook represents information believed to be current best practices, but it is not intended as legal, financial, medical, or consulting advice.

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PART ONE: Overview and Introduction to Professional CGM

Before you begin your journey to incorporate Professional Continuous Glucose Monitoring (Professional CGM) into your practice, it is important to have a thorough understanding of this technology. The following pages describe Professional CGM and introduce this Playbook.

Introduction to the Professional CGM Implementation Playbook
Continuous glucose monitoring, whether personal or professional, is another tool that can help to optimize diabetes management. Although not a new technology, CGM devices are constantly evolving and improving. With the right guidance, Professional CGM can be incorporated into any practice, large or small, specialized or general.

This Playbook brings together fragmented information available from multiple sources to provide an inclusive and unbiased approach to implementation of Professional CGM into your practice. It includes a step-by-step approach to implementation, additional resources and the latest research.

Who Is This Playbook Written For?
This Playbook is for primary care providers and diabetes educators who have an interest in using Professional CGM in their practices.

How Will This Playbook Benefit Me?
Implementation of an efficient and effective Professional CGM Program can be complicated and confusing. The Playbook is designed to help you successfully implement Professional CGM into your practice.

How Do I Utilize This Playbook?
The Playbook is organized into five sections that will assist you in your journey to implement Professional CGM.

Will The Information In This Playbook Become Outdated?
Because of rapid changes in technology and practice recommendations, this Playbook is intended to be a living document and will be reviewed and updated annually, at a minimum, to reflect new information and replace outdated information. Look for the Last Updated date on the second page of the manual to ensure you have the most updated version.
Introduction to Continuous Glucose Monitoring (CGM)

Continuous glucose monitoring has become more widely adopted and utilized in recent years. Devices continue to improve in accuracy, reliability and convenience and insurance coverage is more widespread. Continuous glucose monitoring is considered a standard of care for people treated with intensive insulin programs.

Continuous glucose monitors measure interstitial fluid glucose levels and display numerical and graphic data regarding current glucose status, along with current and projected trends in the glucose. The projected future glucose trend is depicted by directional arrows. This allows users to proactively respond to blood glucose data rather than waiting for hyper or hypoglycemia to develop, therefore offering the ability to take preventive action to avoid hyper or hypoglycemia.

Personal CGM vs. Professional CGM

Continuous glucose monitoring devices are either owned by the user for personal use or owned by the health care center for professional use. Some continuous glucose devices link to other compatible devices, such as insulin pumps, blood glucose meters, smart phones, automated insulin-dosing systems and smart pens. Most CGM devices may be used as stand-alone devices. Some of the devices require periodic calibration with finger stick glucose checks.

Consumers who own personal CGM devices utilize the data in real time to make decisions about their diabetes management. The devices display trend arrows, indicating whether there is a pattern of rising or falling glucose to assist them in problem solving. Clinicians analyze retrospective data, sometimes combined with a user diary or log to gain insights into glycemic patterns.

Three CGM devices are currently available for Professional CGM (September 2019)

- Abbott Freestyle Libre Pro
- Dexcom G4 Platinum
- Medtronic iPro 2

Blinded vs. Unblinded Mode

Professional CGM can be performed in the “blinded” or “unblinded” mode. Unblinded CGM allows people with diabetes to see their glucose data and make treatment decisions about it in real time. Blinded CGM use allows for the capture of glucose data without influencing the individual’s behavior in the moment. Reviewing blinded CGM data with the person with diabetes can produce many “aha moments”, which allows for them to understand how their medications, diet and activity impact their glycemic control.

Of the 3 available Professional CGM’s, only Dexcom allows for both blinded and unblinded mode. The considerations for each are covered in Step 4 in Part 2 of this Playbook.
Components
The Abbott Freestyle Libre Pro consists of a disposable combined glucose sensor/transmitter and a separate touchscreen reader device. The reader for Libre Pro is only used to activate the sensor, but does not go home with the individual. When the sensor is returned, the clinic uses the reader to upload data from the sensor. The sensor is wired just like Dexcom G4 Platinum and Medtronic iPro below.

The Dexcom G4 Platinum CGM consists of three components: a disposable wired sensor which is inserted in the subcutaneous tissue, a data transmitter which is attached to the sensor, and a receiver or smartphone that displays and stores the glucose data. Individuals cannot use a smartphone for the G4, only the receiver.

The Medtronic iPro 2 consists of a disposable wired sensor and a data transmitter, which is attached to the sensor.

IMPORTANT NOTE:
The data transmitter on the Dexcom G4 and the Medtronic iPro 2 need to undergo a cleaning process after being placed on a person with diabetes before the next use.
# Comparison of Professional CGM Devices Currently Available

<table>
<thead>
<tr>
<th>Features</th>
<th>Abbott Freestyle Libre Pro</th>
<th>Dexcom G4 Platinum</th>
<th>Medtronic iPro2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Blinded or Unblinded</strong></td>
<td>Blinded</td>
<td>Either</td>
<td>Blinded</td>
</tr>
<tr>
<td><strong>Wear Time</strong></td>
<td>14 days</td>
<td>7 days</td>
<td>6 days</td>
</tr>
<tr>
<td><strong>Calibration Required?</strong></td>
<td>0</td>
<td>Twice Daily</td>
<td>3-4 times daily</td>
</tr>
<tr>
<td><strong>Components</strong></td>
<td>Disposable wired sensor/transmitter</td>
<td>Disposable wired sensor</td>
<td>Disposable wired sensor</td>
</tr>
<tr>
<td></td>
<td>Separate touchscreen reader device that does not go home with the person with diabetes</td>
<td>Data transmitter attached to the sensor</td>
<td>Data transmitter attached to the sensor</td>
</tr>
<tr>
<td><strong>Care Between Use</strong></td>
<td>Disposable sensor/transmitter</td>
<td>Transmitter and receiver must be cleaned and disinfected</td>
<td>Transmitter must be cleaned and disinfected</td>
</tr>
<tr>
<td><strong>Insertion</strong></td>
<td>Single step process with auto-inserter</td>
<td>Two-step process which inserting sensor and attaching transmitter</td>
<td>Multi-step process which includes inserting and taping both the sensor and transmitter</td>
</tr>
<tr>
<td><strong>Site</strong></td>
<td>Upper Arm</td>
<td>Abdomen</td>
<td>Abdomen</td>
</tr>
<tr>
<td><strong>Downloading/Data Reports</strong></td>
<td>LibreView</td>
<td>Clarity Studio</td>
<td>Carelink</td>
</tr>
</tbody>
</table>
Effectiveness of CGM
Multiple research studies confirm the effectiveness of continuous glucose monitoring. Randomized controlled trials have demonstrated decreased HbA1C and glycemic variability, increased time in range of target glycemia, decreased time in hypoglycemia range and reduction in hypoglycemic events.

Studies have been performed with multiple populations and different device types: people with type 1 and type 2 diabetes, adults and children, personal and Professional CGM. Dr. Anne Peters, Endocrinologist at the Keck School of Medicine at USC, provided a detailed review of CGM studies and outcomes in the Role of Continuous Glucose Monitoring in Diabetes Treatment supplement published by the American Diabetes Association (Chart used by permission, American Diabetes Association, 2018).

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Primary Outcome/Type of CGM</th>
<th>A1C Outcome</th>
<th>Hypoglycemia Change/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ADULTS WITH T1D: A1C PRIMARY OUTCOME</strong></td>
<td></td>
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</tr>
<tr>
<td>Beck et al. (1,2)</td>
<td>Adults with T1D on MDI</td>
<td>A1C reduction / Dexcom G4 Platinum</td>
<td>-0.6%, P&lt;0.001</td>
<td>• Time &lt;70 mg/dL was 43 vs. 80 min/day, P = 0.002</td>
</tr>
<tr>
<td></td>
<td>n = 158</td>
<td></td>
<td></td>
<td>• No difference in severe lows</td>
</tr>
<tr>
<td></td>
<td>Baseline A1C: 8.6%</td>
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<tr>
<td></td>
<td>Parallel arms, 24 weeks</td>
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<tr>
<td>Lind et al. (3)</td>
<td>Adults with T1D on MDI</td>
<td>A1C reduction / Dexcom G4 Platinum</td>
<td>-0.43, P &lt;0.001</td>
<td>• Numerically less time in a hypoglycemic range with CGM</td>
</tr>
<tr>
<td></td>
<td>n = 161</td>
<td></td>
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<tr>
<td></td>
<td>Baseline A1C: 8.6%</td>
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<tr>
<td></td>
<td>Crossover, 26-week arms</td>
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</tr>
<tr>
<td>Sequeira et al. (4)</td>
<td>Underserved adults with T1D on MDI</td>
<td>A1C reduction / Dexcom SEVEN</td>
<td>No significant difference between groups</td>
<td>• No change in rates of hypoglycemia</td>
</tr>
<tr>
<td></td>
<td>n = 25</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Baseline A1C: 8.5%</td>
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<tr>
<td></td>
<td>Crossover, 28-week arms</td>
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<tr>
<td>Tumminia et al. (5)</td>
<td>Adults with T1D on MDI or CSII</td>
<td>A1C reduction / Medtronic Guardian REAL-Time</td>
<td>Only analyzed 14 patients who used CGM ≥40% of the time; in these patients, there was a significant reduction in A1C (P &lt;0.05)</td>
<td>• Risk for hypoglycemia was reduced (time spent&lt;70 mg/dL/day), P&lt;0.05</td>
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<tr>
<td></td>
<td>n = 20</td>
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<tr>
<td></td>
<td>Baseline A1C: ~8.65%</td>
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<tr>
<td></td>
<td>Crossover, 24-week arms</td>
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<tr>
<td><strong>ADULTS WITH T1D: HYPOGLYCEMIA PRIMARY OUTCOME</strong></td>
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<tr>
<td>Bolinder et al. (6)</td>
<td>Adults with T1D on MDI or CSII</td>
<td>Change in time in hypoglycemic range (&lt;70 mg/dL) / Abbott FreeStyle Libre</td>
<td>NS</td>
<td>• Overall, 38% reduction in time in hypoglycemia (~1.24 hours/day, P &lt;0.0001)</td>
</tr>
<tr>
<td></td>
<td>n = 241</td>
<td></td>
<td></td>
<td>• Time in range [3.9–10.0 mmol/L [70–180 mg/dL]; mean difference] improved by 1.0 ± 0.30 hour, P = 0.0006</td>
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<tr>
<td></td>
<td>Baseline A1C: 6.7%</td>
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<tr>
<td></td>
<td>Parallel arms, 6 months</td>
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</tbody>
</table>
### Hermans et al. (7)
- Adults with T1D, most on MDI
- \( n = 41 \)
- Baseline A1C: 8.2%
- Crossover design, 5-day arms; patients were free-living within inpatient research setting

Proportion of time spent hypoglycemic / Dexcom SEVEN PLUS

| N/A | Reduction in time in hypoglycemic range: 125 ± 89 vs. 181 ± 125 min/day, \( P = 0.005 \) |

### van Beers et al. (8)
- Adults with T1D on MDI or CSII with a Gold score \( \geq 4 \)
- \( n = 52 \)
- Baseline A1C: 7.5%
- Crossover, 16-week arms

Mean difference in time in range (4–10 mmol/L [72–180 mg/dL]) / Medtronic Enlite with a MiniMed Paradigm Veo system (used as a monitor)

| NS | Reductions in hypoglycemia (≤ 3.9 mmol/L [70.2 mg/dL]) – 4.7%, \( P < 0.0001 \)
| | Severe hypoglycemia: 14 events with CGM vs. 34 events with SMBG, \( P = 0.033 \)
| | Time in range (mean difference) improved by 9.6%, \( P = 0.0001 \) |

### ADULTS AND CHILDREN WITH T1D: A1C/TIME IN RANGE PRIMARY OUTCOME

#### Battelino et al. (9)
- Adults and children with T1D on CSII
- \( n = 153 \)
- Baseline A1C: 8.1% for adults, 8.6% for children
- Crossover, 6-month arms

A1C reduction / Medtronic Guardian REAL-Time

| A1C difference –0.43% in favor of sensor on, \( P < 0.001 \) | Time spent <3.9 mmol/L (70.2 mg/dL) was 19 vs. 31 min/day, \( P = 0.009 \)
| | Four severe hypoglycemic episodes in sensor on mode, two in sensor off mode |

#### Deiss et al. (10)
- Adults and children with T1D on MDI or CSII \( n = 156 \)
- Baseline A1C: 9.5% in arm 1, 9.7% in arm 2
- Three parallel arms: continuous CGM (arm 1) vs. biweekly 3-day CGM (arm 2) vs. control for 3 months

A1C reduction / Medtronic Guardian REAL-Time

| Arm 1: – 0.6%, \( P = 0.003 \); Arm 2: no difference in A1C | One episode of severe hypoglycemia in each arm |

#### JDRF CGM Study Group (11)
- Adults and children with T1D on MDI or CSII
- \( n = 322 \)
- Three age-groups: ≥ 25 years (\( n = 98 \)), 15–24 years (\( n = 110 \)), and 8–14 years (\( n = 98 \))
- Baseline A1C: ≥ 25 years, 7.6%; 15–24 years, 7.9–8.0%; and 8–14 years, 7.9–8.0%
- Parallel arms, 26 weeks

A1C reduction / DexCom SEVEN, Medtronic MiniMed Paradigm REAL-Time insulin pump and CGMS, and Abbott FreeStyle Navigator

| A1C difference: in those ≥ 25 years of age, –0.53%, \( P < 0.001 \); in those < 25 years of age, no difference; A1C response related to use of CGM | No difference in time spent in a hypoglycemic range or in number of severe hypoglycemic episodes |

#### O’Connell et al. (12)
- Adults and adolescents with T1D on CSII
- \( n = 55 \)
- Baseline A1C 7.3% for intervention group, 7.5% for control group
- Parallel arms, 3 months

Time in range during the 3-month study period / Medtronic MiniMed Paradigm REAL-Time insulin pump and CGMS

<table>
<thead>
<tr>
<th>No difference in primary outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1C was –0.43% lower in the CGM group, ( P = 0.009 )</td>
</tr>
<tr>
<td>Greater reduction in group with more use</td>
</tr>
</tbody>
</table>
### ADULTS AND CHILDREN WITH T1D: HYPOGLYCEMIA PRIMARY OUTCOME

<table>
<thead>
<tr>
<th>Study/Group</th>
<th>Adults and children with T1D on MDI or CSII</th>
<th>Change in time ≤70 mg/dL / DexCom SEVEN, MiniMed Paradigm REAL-Time insulin pump and CGMS, and Abbott FreeStyle Navigator</th>
<th>A1C treatment difference favoring CGM, P &lt;0.001</th>
<th>Time ≤70 mg/dL numerically less frequent (54 vs. 91 min/day) but not significant, P = 0.16</th>
</tr>
</thead>
<tbody>
<tr>
<td>JDRF CGM Group (13)</td>
<td>n = 129 Baseline A1C: 6.4% for CGM group, 6.5% for control group Parallel arms, 26 weeks</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Battelino et al. (14)</td>
<td>n = 120 Baseline A1C: 6.9% Parallel arms, 26 weeks</td>
<td>Time spent in hypoglycemic range / Abbott FreeStyle Navigator</td>
<td>A1C treatment difference favoring CGM: −0.27%, P = 0.008</td>
<td>Time spent &lt;63 mg/dL shorter in CGM group; ratio of means 0.49, P = 0.03</td>
</tr>
<tr>
<td>Heinemann et al. (15)</td>
<td>n = 149 Baseline A1C: 7.3% for control group, 7.6% for CGM group Parallel arms, 26 weeks</td>
<td>Baseline-adjusted hypoglycemia events (glucose ≤3.0 mmol/L [54 mg/dL] for ≥20 minutes) / Dexcom G5 Mobile</td>
<td>No difference in A1C</td>
<td>Adjusted between-group difference in low glucose events: 0.28, P &lt;0.0001</td>
</tr>
</tbody>
</table>

### CHILDREN WITH T1D

<table>
<thead>
<tr>
<th>Study/Group</th>
<th>Children with T1D on MDI or CSII</th>
<th>A1C reduction / Medtronic CGMS</th>
<th>A1C difference at 12 weeks during open vs. blind CGM: −0.39%, P = 0.011</th>
<th>No significant differences in hypoglycemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ludvigsson et al. (16)</td>
<td>n = 27 Baseline A1C: −7.7% Cross-over, 12-week arms; wore CGM for 3 days every 2 weeks</td>
<td>A1C reduction / GlucoWatch G2 Biographer</td>
<td>No significant change in A1C</td>
<td>Sensor use declined from 2.1 to 1.5 times/week because of skin irritation and other issues</td>
</tr>
<tr>
<td>Chase et al. (17)</td>
<td>n = 200 Baseline A1C: 8.0% Parallel arms, 6 months</td>
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</tbody>
</table>

### ADULTS WITH T2D

<table>
<thead>
<tr>
<th>Study/Group</th>
<th>Adults with T2D on MDI</th>
<th>A1C reduction / Dexcom G4 Platinum with an enhanced algorithm</th>
<th>Adjusted mean A1C difference: −0.3%, P = 0.022</th>
<th>No change in hypoglycemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck et al. (18)</td>
<td>n = 158 Baseline A1C: 8.5% Parallel arms, 24 weeks</td>
<td>A1C reduction / Dexcom SEVEN</td>
<td>Difference in A1C: −0.6%, P = 0.002</td>
<td>Hypoglycemia data NA</td>
</tr>
<tr>
<td>Ehrhardt et al. (19)</td>
<td>n = 100 Baseline A1C: 8.2% for SMBG group, 8.4% for CGM group Parallel arms, 2 weeks on/1 week off, 4 cycles over 12 weeks</td>
<td>A1C reduction / Abbott FreeStyle Libre</td>
<td>No difference in A1C overall; difference in A1C if &lt;65 years of age, P = 0.03</td>
<td>No change in hypoglycemia</td>
</tr>
<tr>
<td>Hermanns et al. (7)</td>
<td>n = 224 Baseline A1C: 8.74% in intervention group, 8.88% in control group Parallel arms, 2:1 randomization, 6 months</td>
<td></td>
<td>Time in hypoglycemia (&lt;70 mg/dL) was reduced by 43%, P = 0.000</td>
<td></td>
</tr>
</tbody>
</table>

**ADULTS AND CHILDREN WITH T1D:**
- **Study/Group**: JDRF CGM, Battelino et al., Heinemann et al., Ludvigsson et al., Chase et al.
- **Results**: A1C treatment difference favoring CGM, P <0.001.
- **Findings**: Time ≤70 mg/dL numerically less frequent but not significant, P = 0.16.
- **Data**: Baseline A1C: 6.4% for CGM group, 6.5% for control group.
- **Methods**: Parallel arms, 26 weeks.

**CHILDREN WITH T1D:**
- **Study/Group**: Ludvigsson et al., Chase et al.
- **Results**: No significant differences in hypoglycemia.
- **Findings**: Baseline A1C: 7.7%.
- **Methods**: Cross-over, 12-week arms; wore CGM for 3 days every 2 weeks.

**ADULTS WITH T2D:**
- **Study/Group**: Beck et al., Ehrhardt et al., Hermanns et al.
- **Results**: No significant change in A1C.
- **Findings**: Baseline A1C: 8.5%.
- **Methods**: Parallel arms, 24 weeks.
<table>
<thead>
<tr>
<th>Authors</th>
<th>Study Details</th>
<th>CGM Results</th>
<th>SMBG Results</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yoo et al. (21)</td>
<td>Adults with T2D on oral agents or insulin</td>
<td>A1C reduction / Medtronic Guardian REAL-Time</td>
<td>Improvement in A1C greater in CGM group, -0.5%, P = 0.004 (CGM: from 9.1 ± 1.0 to 8.0 ± 1.2%, P &lt;0.001; SMBG: from 8.7 ± 0.7 to 8.3 ± 1.1%, P = 0.01)</td>
<td>No significant changes in hypoglycemia; In real-time CGM, reduced caloric intake, weight, BMI, and postprandial glucose level; increased physical activity</td>
</tr>
<tr>
<td>Garg et al. (22)</td>
<td>Adults with T1D or T2D on insulin</td>
<td>Time spent in high, low, and target glucose zones / Dexcom STS sensor</td>
<td>Improvement in A1C greater in CGM group, ~0.5%, P = 0.004 (CGM: from 9.1 ± 1.0 to 8.0 ± 1.2%, P &lt;0.001; SMBG: from 8.7 ± 0.7 to 8.3 ± 1.1%, P = 0.01)</td>
<td>No significant changes in hypoglycemia; Improvement in A1C greater in CGM group, ~0.5%, P = 0.004 (CGM: from 9.1 ± 1.0 to 8.0 ± 1.2%, P &lt;0.001; SMBG: from 8.7 ± 0.7 to 8.3 ± 1.1%, P = 0.01)</td>
</tr>
<tr>
<td>New et al. (23)</td>
<td>Adults with T1D or T2D on MDI or CSII</td>
<td>Time spent outside of target range / Abbott FreeStyle Navigator; 1/3 CGM with no alarm, 1/3 CGM with alarm, 1/3 SMBG</td>
<td>No difference in A1C or time spent outside of target range</td>
<td>Less time in hypoglycemia range in group with alarms compared to SMBG group, P = 0.03</td>
</tr>
<tr>
<td>Cooke et al. (24)</td>
<td>Adults with T1D or T2D treated with at least twice-daily insulin injections</td>
<td>A1C reduction / GlucoWatch G2 Biographer vs. Medtronic MiniMed CGMS (blinded)</td>
<td>No significant difference in A1C reduction</td>
<td>No reduction in hypoglycemia; possibly an increase</td>
</tr>
<tr>
<td>Feig et al. (25)</td>
<td>Adult women with T1D on MDI or CSII who were pregnant or planning pregnancy</td>
<td>A1C reduction / Medtronic Guardian REAL-Time or MiniMed MiniLink</td>
<td>A1C difference -0.19%, P = 0.0207 in pregnant women; no A1C difference in women planning pregnancy</td>
<td>Comparable severe hypoglycemia events (18 vs. 21) and time spent hypoglycemic (3 vs. 4%); Neonatal health outcomes: fewer LGA babies, fewer neonatal ICU stays for &gt;24 hours, and fewer neonatal hypoglycemia events</td>
</tr>
<tr>
<td>Secher et al. (26)</td>
<td>Adult women with T1D or T2D who were pregnant</td>
<td>LGA babies / Medtronic Guardian REAL-time CGM with Sof-Sensor</td>
<td>No difference in A1C</td>
<td>No difference in number of LGA babies</td>
</tr>
</tbody>
</table>
**REFERENCES**


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**Table:**

<table>
<thead>
<tr>
<th><strong>Juvenile Diabetes Research Foundation; LGA, large-for-gestational-age; NA, no applicable; NS, non-significant; T1D, type 1 diabetes; T2D, type 2 diabetes.</strong></th>
</tr>
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<tr>
<td><strong>• Some reduction in maternal weight gain</strong></td>
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<th><strong>Parallel arms; women were asked to wear CGM intermittently early (second trimester) or late (third trimester) or perform SMBG</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>• Adult women with GDM at 24–28 weeks of pregnancy</strong></td>
</tr>
<tr>
<td><strong>• n = 106</strong></td>
</tr>
<tr>
<td><strong>• Baseline A1C: 5.8% in SMBG group, 5.7% in CGM group</strong></td>
</tr>
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**Guidelines/Position Statements Pertaining to CGM**

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</thead>
<tbody>
<tr>
<td>Diabetes educators provide the coaching needed to help people with diabetes reap the benefits of CGM technology by utilizing the information to make smarter diabetes management decisions, reduce risk of hypoglycemia and hyperglycemia and thereby improve the quality of life.</td>
<td>Real-time CGM in conjunction with intensive insulin regimens is a useful tool to lower HbA1C in adults with type 1 diabetes who are not meeting glycemic targets.</td>
<td>Real-time CGM is recommended for adults with type 1 diabetes who are willing and able to use device on a nearly daily basis.</td>
<td>CGM is recommended for adult and pediatric patients with type 1 diabetes, particularly for those with history of severe hypoglycemia and hypoglycemia unawareness, and to assist in the correction of hyperglycemia in patients not at goal.</td>
<td>CGM should be considered in conjunction with HbA1C monitoring for glycemic status assessment and therapy adjustment for all patients with type 1 diabetes and patients with type 2 diabetes treated with intensive insulin therapy who are not achieving glucose targets, especially if the patient is experiencing problematic hypoglycemia.</td>
</tr>
</tbody>
</table>
| Real-time CGM may be a useful tool in those with hypoglycemia unawareness and/or frequent hypoglycemia. | Short-term, intermittent, real-time CGM is recommended for adult patients with type 2 diabetes (not on prandial insulin) who have HbA1C greater than or equal to 7.0%. | There are no recommendations for patients with type 2 diabetes due to limited data. | Benefits of Professional CGM

Intermittent use of Professional CGM has many benefits to the person with diabetes and the health care provider including:

- Identification of extremes in blood glucose levels
- Identification of Time in Range “TIR” of blood glucose results and if individual person with diabetes is meeting their desired targets
- Assessment of nocturnal glucose patterns
- Assessment of how well the current diabetes treatment plan is working and assess for need to change treatment plan
- Use as a teaching tool to help the person with diabetes understand the effects of factors such as food intake, exercise and diabetes medications on glucose levels
- May use as a test run to see if the individual would want to own a personal CGM; some insurances may require this

**Candidate Selection**

Many people with diabetes can benefit from an evaluation with Professional CGM. Some good examples include those with:

- Gastroparesis
- Discordant HbA1C and fingerstick glucose readings
- Post-prandial hyperglycemia
- Hypoglycemia unawareness
- Pregnancy (Note: This is not approved.)
- Lack of regular monitoring of fingerstick glucose levels
- Renal disease

**Additionally:**

- Finger stick data is limited; CGM allows the HCP and person with diabetes to see BG 24/7
- Those who need to do multiple finger sticks daily
- When the HCP needs more data
- When individuals are considering personal CGM
- When insurance will not cover personal CGM, only Professional CGM
Primary Care Case Studies

Case Study 1

Robert G. is a 66-year-old male with a 5-year history of Type 2 diabetes followed by primary care. Weight 201 pounds and BMI 32.44. Diabetes medications: Basaglar 26 units every night and Humalog 8 units before meals. A1C was 6.9% but his home glucose readings were higher than 200 mg/dl whenever he checked them, which sometimes was only once daily in the evening after work. His PCP ordered a diagnostic CGM because blood glucose values and A1C did not match.

He wore the Libre Pro CGM for 12 days and kept a detailed food, medication and activity log.

The 12-day report showed that his blood glucose levels were dropping low overnight and also in the afternoon when he skipped lunch. His blood glucose values trended high before dinner. He admitted to snacking in the late afternoon if he was feeling a bit light-headed after not having had time to eat lunch. The snacks he had written down tended to be 30-60 grams in carbohydrate.

The diabetes educator discussed with him how to best distribute his carbohydrates throughout the day and advised that he not skip meals. She also reviewed with him the best times to check his blood glucose and what the goals were for him.

After interpreting the CGM, his PCP decreased his Basaglar to 24 units and decreased his breakfast Humalog dose to 7 units. Other doses remained the same. He was instructed to check his blood glucose before meals and at bedtime and to call these results in one week to the diabetes educator.

Robert has subsequently decided to pursue CGM for personal use and is waiting to hear if his insurance company will authorize this for him.

Shared with permission by Mary S. RN, CDE
Case Study 2

This case involves a 76-year-old man with type 2 diabetes of 10 years’ duration. He takes extended-release glipizide, 5 mg in one pill daily; sitagliptin, 100 mg in one pill daily; and glargine insulin, 20 units subcutaneously at bedtime. He was checking blood glucose one or two times daily, usually in the morning, and all his SMBG results were within his target range. However, his A1C was 9.0%, and the PCP had increased his basal insulin dose despite his objections that he was having frequent hypoglycemia and would wake up many times shaking in the middle of the night. The PCP felt that he could not be having significant hypoglycemia because there were no documented low SMBG results and his A1C was elevated at 9.0%.

He was referred for diabetes education and a 6-day blinded Professional CGM study. The CGM results indicated that his blood glucose levels were dropping by 200 mg/dl every night, and he was experiencing blood glucose levels < 70 mg/dl. The patterns also revealed lower morning glucose levels with sustained elevated blood glucose after meals throughout the day.

The CDE reviewed and discussed the CGM results with him. Because he was checking his blood glucose only in the morning, he was surprised by the pattern of elevation after meals, the rise of his glucose level throughout the day, and the significant drop in blood glucose values overnight related to his basal insulin and shown below.

After the CGM study, his basal insulin dose was decreased to 12 units and switched to mornings instead of bedtime, his glipizide was discontinued, and his sitagliptin was continued. He was started on 4 units of premeal rapid-acting insulin before supper because it is his biggest meal of the day, and he does not always eat breakfast or lunch.

After 3 months, he was free of hypoglycemia symptoms at night, and his A1C had dropped to 7.6%. He achieved his A1C target of < 8.0% (a less intense goal because of his history of comorbidities, including coronary heart disease and chronic kidney disease).

-CGM trace. Nocturnal hypoglycemia and elevated glucose levels after meals were demonstrated on 4 days of CGM. Different colors represent different days.

Clinician Readiness to Promote CGM
How ready are you and your staff to promote Professional CGM in your practice? Tanenbaum et al., in 2018, surveyed 209 diabetes care providers who treat people with type 1 diabetes. Three clinician personas emerged regarding readiness to promote continuous glucose monitoring.

- **Ready clinicians** (20% of sample; 24% physicians, 38% certified diabetes educators – CDEs) had positive technology attitudes, had clinic time to work with people using CGM and found it easy to keep up with technology advances.
- **Cautious clinicians** (41% of sample; 17% physicians, 53% CDEs) perceived that their patients had many barriers to adopting CGM and had less time than the ready group to work with people using CGM data.
- **Not yet ready clinicians** (40% of sample; 9% physicians, 79% CDEs) had negative technology attitudes and the least clinic time to work with CGM data. They found it difficult to keep up with technology advances.

Overcoming Therapeutic Inertia
Therapeutic inertia is a well-known problem in the management of diabetes. Treatment intensification may be delayed for a prolonged period due to several reasons. Kamlesh Khunti, FMedSci, FRCGP, FRCP, MD, PhD, presented an overview of the scope and impact of therapeutic inertia as well as clinician barriers related to therapy intensification reported in the American Diabetes Association’s publication, *Summary of the Proceedings of the American Diabetes Association Summit - Overcoming Therapeutic Inertia: Accelerating Diabetes Care FOR LIFE.*

These barriers include the following:

- lack of time
- lack of resources
- lack of training and education
- suboptimal patient medication-taking behavior
- perceptions about patients’ ability and willingness to follow treatment protocols
- hypoglycemia concerns and management of comorbidities.

In this same publication, session participants were asked to share their ideas of the causes and impact of therapeutic inertia and to summarize that in one word. Words identified to describe the top contributors to therapeutic inertia were “time,” “cost,” “fear,” “apathy” and “overwhelmed.” Words identified to describe the solutions to address therapeutic inertia were “education” and “time.”

A Professional CGM program can address therapeutic inertia by identifying glycemic patterns and changing the treatment plan to address problem areas that are uncovered. Changing the treatment plan does not only entail pharmaceutical intervention, but also, very importantly, includes an analysis of lifestyle factors and behavioral issues and a plan to overcome these obstacles. A diabetes educator is the best person on your team to address these topics with people with diabetes, as they are skilled at coaching persons with diabetes in all aspects of self-management of their condition using an evidence-based framework, the AADE7®Self-Care Behaviors.
Interpretation of CGM Data and Reports
The health care provider interprets the CGM reports retrospectively and evaluates for glycemic excursions above/below target range, seeking to identify patterns and potential causes for these excursions.

Device download reports vary by manufacturer and include differing data presentations; however, there has been a recent push to focus on use of the Ambulatory Glucose Profile (AGP), which was developed by the Park Nicollet International Diabetes Center (IDC) in Minneapolis, Minnesota. The use of one report would help to standardize care. The AGP includes summary statistics, a glucose profile graph and an insulin profile graph or glucose daily calendar graphs.

Example of AGP Report

AGP Report from International Diabetes Center.
The 2017 *International Consensus on Use of Continuous Glucose Monitoring* report published in Diabetes Care provides a detailed description of the 14 key metrics that can be analyzed when reviewing retrospective data.

More recently (2019), the International Consensus on Time in Range identified standardized clinical targets for CGM data interpretation, as follows:

<table>
<thead>
<tr>
<th>Number of days CGM is worn</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 days is recommended</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Percentage of time CGM is active</th>
</tr>
</thead>
<tbody>
<tr>
<td>70% of data from 14 days is recommended</td>
</tr>
</tbody>
</table>

**Mean glucose**

**Glucose Management Indicator (GMI)**

This used to be called the estimated A1C (eA1C) but now uses an updated formula for converting CGM-derived mean glucose to an estimate of current A1C level.

**Coefficient of Variation (CV)**

This is a measure of glycemic variability. A CV of less than or equal to 36% is considered acceptable, >36% is considered unstable and intervention is needed.

**Very High Time Above Range (TAR)**

% of readings and time >250 mg/dl

**High Time Above Range (TAR)**

% of readings and time 181-250 mg/dl

**Time In Range (TIR)**

% of readings and time 70-180 mg/dl

**Low Time Below Range (TBR)**

% of readings and time 54-69 mg/dl

**Very Low Time Below Range (TBR)**

% of readings and time <54 mg/dl

The first priority is to reduce the time spent below range (work to eliminate hypoglycemia) and then focus on decreasing time above range or increasing time in range.
Glucose time in range (TIR) is another important measure and Dr. Richard Bergenstal, in 2018, identified correlations of TIR and HbA1C as follows:

<table>
<thead>
<tr>
<th>Time in Range (TIR) %</th>
<th>Average HbA1C</th>
</tr>
</thead>
<tbody>
<tr>
<td>40%</td>
<td>8.1%</td>
</tr>
<tr>
<td>50%</td>
<td>7.7%</td>
</tr>
<tr>
<td>60%</td>
<td>7.3%</td>
</tr>
<tr>
<td>70%</td>
<td>6.9%</td>
</tr>
<tr>
<td>80%</td>
<td>6.5%</td>
</tr>
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</table>

Continuous Glucose Monitoring (CGM) Data Interpretation Using the Ambulatory Glucose Profile (AGP)*

Step 1 Confirm that adequate data are available. For current CGM users, a minimum of 70% of 2 weeks of data is recommended. Fewer days are needed when professional CGM systems are used.

Step 2 Print out the AGP and ask patients to describe their daily self-management. When are they taking their insulin and how much? When do they wake? When do they eat? Do they exercise and, if so, what type of exercise and when are they doing it? Document this information on the AGP printout.

Step 3 Ask the patients what they see in the AGP and why they think it may be important. Then listen. Interactive discussion with patients allows them to better understand how their insulin, food and other factors affect their glucose levels and also helps clinicians identify knowledge deficits or behaviors that may not support glycemic goals.

Step 4 Look for problematic glycemic patterns in the following order of priority:
1) Hypoglycemia, 2) Hyperglycemia, 3) Wide glycemic variability
Review the overall glucose profile (initial view) to determine the time of day when patterns are occurring, then review the daily graphs to double-check patterns to see if they are clustered on certain days.

Step 5 Encourage patients to reflect on what they think may be causing the problem and discuss potential solutions.

Step 6 Collaboratively develop an action plan. Make sure patients fully understand the changes they will be making and that they have the knowledge/skills to implement the plan.

Step 7 Make a copy of the marked up AGP printout for the patient and enter the original into the electronic medical record (EMR). If electronic entry is not possible, copy and paste the AGP into the EMR as a progress note.

*An expanded teaching tool is available at https://www.idcpublishing.com/.

I always assumed that Professional CGM was only helpful for someone on multiple insulin injections per day.

One of my patients on sulfonylurea medication came to me complaining of feeling sick every morning. Her recent HbA1C was 8.8% and her medication had been upwardly adjusted by another provider. She only checked her blood glucose once daily in the evening, due to difficulty affording the test strips, and her home results were in the 200 mg/dl range.

I decided to place a Professional CGM to see if it would uncover any useful information. When she came in for a return visit and her Professional CGM was downloaded, we reviewed it together. She was experiencing significant hypoglycemia overnight every night, with results dropping into the 50s mg/dl range. Due to “feeling sick” in the morning, she would consume a lot of carbohydrates throughout the day and would subsequently experience higher than target range glucose levels later in the day.

We changed her treatment plan and the hypoglycemia was eliminated and she felt much better.

- Shared with permission Patricia S., Endocrinology CRNP
Dr. Kathleen Eubanks-Meng is a primary care physician who implemented professional continuous glucose monitoring into her practice 18 months ago. “The process gets smoother over time.” Her practice experienced some problems with the first device that they chose not being returned to the clinic. They have now switched to a disposable option which they have found makes for a smoother process. They do a prior authorization process and let the patient know what the cost may be. They have found that some people choose not to do the Professional CGM at the start of the year because they have not met their deductible yet. The practice keeps a recall list and checks with them again in 90 days.

Physicians order and interpret the Professional CGMs – the NP and PA can order and interpret as well. The CGM is placed by the tech or the LPN who also provides instruction on keeping the diary throughout the process. The individual is scheduled to wear the device for either 7 or 14 days. When they return, the same staff person that placed the CGM will remove it and download the device. The downloaded report is then sent to the ordering physician. *

The physicians were trained in CGM interpretation either by the device manufacturers or by on-line/live CME programs. They utilize a documentation template to report the findings and this is attached with an order set for patient instructions/disposition, which may include a visit to the clinic diabetes educator.

A follow up appointment is then scheduled in 5-7 days to meet with the physician and to go over the report. The billing for the entire process takes place after the interpretation is complete to ensure the loop is fully closed.

Dr. Eubanks-Meng reports, “The Professional CGM Program has been beneficial to both persons with diabetes and the healthcare providers.” Her program is a revenue generator and has also improved the diabetes metrics within the practice.

*An MD, NP, and PA are all qualified to interpret and act on CGM results.
PART TWO:
Getting Started –
Steps to Develop a
Professional CGM Program

STEP
1. Identify the Need for Professional CGM Program
2. Establish the Clinical Team and Define Roles
3. Define Billing Process
4. Evaluate the Manufacturers and Determine Which Device(s) to Purchase
5. Contract with Manufacturer and Ongoing Inventory Management
6. Train the Staff
7. Design the Workflow
8. Prepare the Clinic/Team
9. Prepare the Person with Diabetes
10. Implement the Program
11. Evaluate the Program
12. Follow-Up/Plan for Future
STEP 1: IDENTIFY THE NEED FOR PROFESSIONAL CGM PROGRAM

Establish genuine need for your Professional CGM Program.

Begin by outlining benefits to the people with diabetes, providers and practice. What does your practice hope to gain by implementing this program? Will it solve current problems? Will it help improve the diabetes metrics in your practice? Are you doing all you can to reduce your patient’s HbA1C levels and to optimize their management currently?

Once this genuine need is clearly identified, you will know that you are headed in the right direction.

Checklist of Items to Accomplish During this Phase

☐ Meet with administration and business leaders to discuss challenges and value of a Professional CGM Program

☐ Meet with the other providers or diabetes educators to identify current challenges with managing people with diabetes and opportunities to improve [See Worksheet 1]

☐ Meet with support staff to identify any concerns they have and obtain their buy-in

☐ Identify outcomes of a successful Professional CGM Program, both to people with diabetes and to the practice [See Worksheet 2]

QUICK TIP:
Reach out to colleagues at other practices with an already established Professional CGM Program and network with them about what worked – and what didn’t go as smoothly as hoped – when getting the program off the ground. Continue to call on them and utilize them as a resource as you create and implement your program. The experience and advice of these key people will be invaluable to you as you move forward.
STEP 2:
ESTABLISH THE CLINICAL TEAM AND DEFINE ROLES

Finding the right composition of the team is vital.

Enthusiastic and well-qualified team members will ensure a successful launch of the program. In this phase you will need to identify who will be on the team and what their roles will be. A diabetes educator/certified diabetes educator (CDE) is valuable to the team, if you have one on your staff. The diabetes educator can help the individual understand how various lifestyle factors and self-care behaviors affect their diabetes management.

Checklist of Items to Accomplish During this Phase

- Identify the members of your team
  See Worksheet 3

- Define roles and responsibilities of each team member
  See Worksheet 4
  See Worksheet 5

- Meet as a team regularly

- Seek ongoing feedback from all involved parties

“Talent wins games, but teamwork and intelligence win championships.”

- Michael Jordan

QUICK TIP:

Anticipate barriers and be prepared to address them. Pay attention to the climate of the team. Seek ongoing ideas from all and don’t be averse to changing direction if warranted. Actively seek to minimize disruption to current workflow.
**STEP 3: DEFINE BILLING PROCESS**

Defining the billing process before you begin will help ensure that all potential roadblocks are anticipated, identified and addressed. Make a list of the common insurance payors that your patients may have. Investigate what their policies are surrounding Professional CGM use. Educate staff on the billing codes to utilize for Professional CGM.

*See Worksheet 6*

**Checklist of Items to Accomplish During this Phase**

- Identify the team member to be accountable for coordination of insurance benefits and requirements
- Provide an in-service for staff on coding, billing and documentation requirements for Professional CGM
- Identify team member(s) to perform ongoing coding and billing audits of individuals in the program

**QUICK TIP:**

Mapping out the billing process before you begin will help prevent the delivery of non-covered services. Insurance rules get updated frequently, so you may need to reach out at least annually to determine if any new policies have been put into place surrounding Professional CGM.
STEP 4: EVALUATE MANUFACTURERS AND DETERMINE WHICH DEVICE(S) TO PURCHASE

Refer to table that appeared earlier in this Playbook, to evaluate the features of the various devices. All three manufacturers provide excellent resources and support for their products. See Worksheet 7

Things to consider when making your choice of device:

- **Care Between Use.** If you choose the Dexcom G4 Platinum or Medtronic iPro2, you will need to have an area available for the cleaning and disinfecting of the transmitters, as well as staff available to perform this duty. The Abbott Freestyle Libre Pro is disposable so you will not need a cleaning station for it.

- **Logging Other Events.** Event markers, such as exercise, food intake and medications taken, can be logged electronically through the Dexcom Studio and Medtronic iPro2 myLog app. When using the Abbott Freestyle Libre Pro, these events are logged on a paper diary and need to be compared side-by-side with the glucose data download.

- **Length of Wear.** Determine if length of time for sensor wear is important. The Abbott Freestyle Libre Pro has the longest wear time, 14 days.

- **Blinded or Unblinded.** Determine need for blinded versus unblinded device.

- **Data/Reports.** Compare the download reports for ease of interpretation and completeness.

Checklist of Items to Accomplish During this Phase

- Meet with the manufacturer representatives for the devices that you are interested in
- Schedule vendor presentations of devices with members of your team
- Evaluate each vendor for information technology support, customer service and business processes
- Choose a vendor that will support you during the implementation period and beyond

**QUICK TIP:**

Consider testing all three devices to fully understand the processes involved surrounding each of them.
STEP 5:
CONTRACT WITH MANUFACTURER AND ONGOING INVENTORY MANAGEMENT

Once you have determined which device you will purchase and stock in your program, you will need to make a contract with the vendor. You will want to address customer service, IT support and other business needs.

For example, how many devices do you need? The Abbott Freestyle Libre Pro system utilizes a disposable attached sensor and transmitter unit along with a multiple use reader. The Dexcom G4 Platinum utilizes disposable single use sensors along with a reusable transmitter. The Medtronic iPro2 utilizes disposable single use sensors along with a reusable transmitter. You want to ensure that your inventory items will not expire before they are used.

See Worksheet 8

Checklist of Items to Accomplish During this Phase

☐ Determine where you will store your device components

☐ Identify team member responsible for inventory management and ensuring the device is cleaned and charged before being placed on another patient

☐ Does software need to be installed for downloading the device? Which computer(s) will you install it on? Do you need approval from your internal IT support?

☐ Place vendor contact information and customer support contact information in a prominent location for all staff to access as needed

☐ Estimate the budget required to obtain and maintain device components

☐ Outline clear and measurable goals for vendor contract. This will be very individual. The support needed (i.e., IT trouble shooting and other issues) is local and depends on the quality of the representative the company has in the area. Make a relationship with that person.

QUICK TIP:

Good vendor relations are an important piece of the success of your Professional CGM Program. Meet with your local representative at regularly scheduled intervals. Optimal inventory management will be a vital factor when calculating the ROI (return on investment) of your program.
STEP 6: TRAIN THE STAFF

Staff will need to be trained on patient selection, use/maintenance of the device, providing instructions to patient, diagnosis/coding/billing, documentation, interpretation and the process for dissemination of results to patient.

Checklist of Items to Accomplish During this Phase

☐ Develop protocol that lists characteristics that would make individuals most likely to benefit from Professional CGM
  See Worksheet 9

☐ Set up vendor training sessions for all involved staff

☐ Develop staff competencies, so their skills will be documented

☐ Set up provider training for diagnosis/coding/billing, interpretation and documentation of download

☐ Start planning annual training refresher now

QUICK TIP:

Providing thorough pre-implementation training will help ensure a smooth start to the program. Solicit staff feedback frequently during and after the training sessions. Consider recording the training sessions so that new staff joining the program in the future will have access to it.
STEP 7: DESIGN THE WORKFLOW

Adding a Professional CGM Program to your practice will require changes to your current workflow. You have already identified the roles of your team members, so you are aware of what new responsibilities they will be taking on. It is helpful to document the Professional CGM process from start to finish so you have a clear understanding of all steps.

See Worksheet 10

Checklist of Items to Accomplish During this Phase

☐ Seek input from all team members regarding the design of the workflow

☐ Document visit from beginning to end

☐ Update existing protocols or document new ones to accommodate this new workflow in daily practice

☐ Plan for enhanced staffing levels as you roll out the new program

☐ Provide support and resources surrounding the new workflow

☐ Solicit staff feedback every step of the way

☐ Plan for ongoing scheduled evaluation of workflow

☐ Determine what data you will want to collect ongoing

QUICK TIP:

It is important to consider all perspectives when designing the workflow, including that of the person with diabetes, the support staff and the providers. You may want to appoint a patient representative to assist with design, implementation and evaluation of the workflow to ensure that you fully understand their perspective. As you learn and grow, your program will continue to adjust its workflow.
STEP 8:
PREPARE THE CLINIC/TEAM

Ensure that all team members are aware of their roles and responsibilities. Proper staff preparation will make sure that the team is on board with the plan and motivated to put in their best effort to help make it a success. Remember to start process evaluation as soon as the implementation stage kicks off.

Checklist of Items to Accomplish During this Phase

☐ Host a program launch kick-off event and review roles/responsibilities

☐ Identify staff “superusers” who can serve as resources to others

☐ Have vendor and IT available during implementation

☐ Make device procedure reference materials and troubleshooting guides widely available

☐ Provide a forum for staff to provide feedback and suggestions

QUICK TIP:

Keep an open communication line with the team members and involved staff. It is important that the team feels that this is a collective effort and that everyone’s feedback is equally important.

“Management is doing things right; leadership is doing the right things.”

– Peter F. Drucker
STEP 9: PREPARE THE PERSON WITH DIABETES

The Professional CGM Program will require frequent and active input from the person with diabetes. It is vitally important to hold a conversation with them that provides education for them about the importance of tracking food intake, exercise and diabetes medication timing. They need to know that the interpretation of the results requires these inputs for best comprehension.

Checklist of Items to Accomplish During this Phase

☐ Develop a handout which discusses the benefits of Professional CGM and the importance of keeping a log of food intake, activity and diabetes medication

See Worksheet 11

☐ Check insurance benefits for Professional CGM. Complete prior authorization with insurance company if needed. Write letter of medical necessity if needed. Most insurance, including Medicare and Medicaid, will cover Professional CGM 2x year – but this number should be known and verified.

☐ Have person sign consent form for insertion of sensor if needed

☐ Schedule return appointment for patient to return the sensor and review interpretation with provider. Many individuals will mail back their sensor. Some providers will provide their interpretations via telephone.

QUICK TIP:

Make the person with diabetes the centerpiece of the program. Remember that the most prepared person will yield the best interpretation of the data. Spend time up front on education and support to ensure their understanding of the process and goals of the program.
STEP 10: IMPLEMENT THE PROGRAM

You are now ready to try out your new program! All the pieces should be in place. Stress the importance of educating and preparing the patient with the team. Solicit feedback and ideas from staff and patients throughout the implementation process. Start tracking success measures at program initiation.

Checklist of Items to Accomplish During this Phase

☐ Provide on-site technical and product support resources to staff during launch

☐ Perform frequent check-ins with staff at this beginning phase of the program implementation

☐ Schedule a weekly staff meeting to discuss how things are going

☐ Start collecting any data that you will want to analyze ongoing now

☐ Walk through the process from start to finish

QUICK TIP:

If possible, try to have some cushion in your staffing during this time. This will enable staff to take the time necessary to fully learn and practice the new procedures and processes. Communicate frequently with your support staff to identify any challenges or obstacles to program success. Utilize vendor support and IT support to ensure a smooth implementation.
STEP 11: 
EVALUATE THE PROGRAM

Program evaluation is an ongoing process. Refer often to the metrics of program success that you have identified. Celebrate once you are meeting these success points. If you are not meeting them, determine what the obstacles and challenges are. Practice continuous quality improvement. Be thoughtfully and quickly responsive to suggestions/ideas/feedback.

**Checklist of Items to Accomplish During this Phase**

- Compile and sort staff feedback
- Analyze and evaluate the data that you have collected
- Compare diabetes outcome post-Professional CGM Program to pre-program outcomes
- If you are not meeting success metrics, re-evaluate your program process and amend as necessary
- If you are meeting success metrics, disseminate the results widely
- Meet with the entire team to determine next steps. Is program the right size? Does it have the right composition of staff? Is the device inventory satisfactory?

**QUICK TIP:**

Establish a timeline for ongoing program evaluation. A program may not attain the expected measures of success in the first few rounds of evaluation. Staff will become more efficient with the program processes as time goes by. Ease of use will improve, and staff confidence and competence will show ongoing improvements as well.
STEP 12: FOLLOW-UP/PLAN FOR FUTURE

Planning for the future of your Professional CGM program is a crucial component of a successful program. What are the next steps for your program? Do you want to establish a satellite location? Do you want to start incorporating personal CGM into your practice? Do you want to start working with patients remotely? Do you want to offer an additional CGM product in your program?

Checklist of Items to Accomplish During this Phase

☐ Hold a meeting with the entire team to discuss future goals for the program
☐ Explore feasibility of goals

QUICK TIP:

Remember to include administration when planning for the future of the program.
PART THREE: Worksheet Resources

The following resources have been developed to enhance your program design, implementation and evaluation as detailed in the Playbook.

“Alone we can do so little; together we can do so much.”

-Helen Keller
Worksheet 1:
Evaluate the Value (Pros) and Challenges (Cons)
of Professional CGM Program

<table>
<thead>
<tr>
<th>PROS</th>
<th>CONS</th>
</tr>
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<tbody>
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</tbody>
</table>

Some examples of pros:
Improve self-care outcomes, improve diabetes metrics, create a revenue stream.

Some examples of cons:
Increased workload to staff, pushback from providers, need for dedicated space for the program, etc.
Worksheet 2:
Identify Outcomes of a Successful Professional CGM Program

List the criteria for your program success. Examples may be improved self-care outcomes (be specific about your population), meet diabetes care metrics, create a new revenue source, etc.

Place this list in a prominent location to allow for frequent review.
Worksheet 3:
Form Your Team

How many teams do you need?

Often there will be several sub-teams: A Leadership Team that makes high level decisions, a Management Team that is accountable for day-to-day operations and an Advisory Team that may be partly composed of customers.

List your team structure and team members below:

<table>
<thead>
<tr>
<th>LEADERSHIP TEAM</th>
<th>MANAGEMENT TEAM</th>
<th>ADVISORY TEAM</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>
Worksheet 4: Define Team Member Roles and Responsibilities

Leadership Team:
- Identify need for the project
- Provide administrative support for the project
- Identify key members of management team
- Market the project
- Vendor contracting and relations
- Define and evaluate success

Management Team:
- Responsible for day-to-day operations
- Identify team members and roles
- Implement program
- Provide ongoing support to team members
- Evaluate program continuously

Advisory Team:
- Identify need for the project
- Partner with the patient and evaluate patient satisfaction with program
- Participate with program implementation and evaluation
### Worksheet 5:
Identify Program Processes and Assign Tasks to Team Members

**Examples:**

<table>
<thead>
<tr>
<th>Program Processes/Tasks</th>
<th>Team Member Assigned</th>
</tr>
</thead>
<tbody>
<tr>
<td>Billing/Prior Authorization/Pre-certification</td>
<td></td>
</tr>
<tr>
<td>Inventory Management</td>
<td></td>
</tr>
<tr>
<td>Placement of Device</td>
<td></td>
</tr>
<tr>
<td>Patient Instruction</td>
<td></td>
</tr>
<tr>
<td>Download of Device Data</td>
<td></td>
</tr>
<tr>
<td>Cleaning of Device (if applicable)</td>
<td></td>
</tr>
<tr>
<td>Interpretation of Device Data</td>
<td></td>
</tr>
<tr>
<td>Communication of Plan to Patient</td>
<td></td>
</tr>
<tr>
<td>Analyze Outcomes Data</td>
<td></td>
</tr>
<tr>
<td>Market the Program</td>
<td></td>
</tr>
</tbody>
</table>
### CPT Codes for Placement and Interpretation of Professional CGM

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Explanation of Code</th>
<th>Who Can Perform Duty</th>
</tr>
</thead>
<tbody>
<tr>
<td>95250</td>
<td>This code is used both for the placement of Professional CGM and the downloading of the data. Placement can be performed by multidisciplinary health care providers, as long as it is within their scope of practice. This code should only be reported once per month per patient, although this may vary by payer.</td>
<td>Examples of staff who may perform this duty include: MD/DO, NP/PA, CDE, RD, RN</td>
</tr>
<tr>
<td>95251</td>
<td>This code is used for interpretation of Professional CGM. Does not require a face-to-face visit.</td>
<td>Interpretation can be performed by MD/DO or NP/PA</td>
</tr>
</tbody>
</table>

**Notes:**
- Both codes may only be used if the patient wears the device for a minimum of 72 hours.
- Both codes may only be reported once per month per patient, although this may vary by payer.
- An E/M Code (Evaluation and Management) can be billed on the same day of either of these codes as long as a distinct and separate E/M service was medically necessary and provided over and above the Professional CGM service. In this case, the modifier -25 must be attached to the E/M code.

### Checklist for payors:

- Do they have a formal policy for Professional CGM?
- Do they require prior authorization?
- How often do they allow Professional CGM to be performed on a particular patient?
Worksheet 6: Billing and Coding (continued)

Flowchart of billing and coding process

1. Determine necessity for Professional CGM
2. Obtain insurance precertification/authorization
3. Ensure that note and diagnosis code support Professional CGM and show interpretation was utilized to address need (i.e., CGM indicated low BG overnight. Insulin program will be adjusted to prevent low BG.)
4. Place -25 modifier to E/M code if billed on same day of service
5. Perform routine audits of CGM billing process and reimbursements

**Items to document in the interpretation note:**
(you can amend this note content as needed by your practice)

- Duration that the patient wore the Professional CGM device (needs to be >72 hours)
- Current diabetes treatment plan
- Current HbA1C
- Time in target range, time above and below target range
- Patterns of hypo/hyperglycemia
- Any changes recommended to treatment plan
- Any further actions, such as referral to diabetes educator
- Copy of the device download
### Worksheet 7: 
**Device Choice Algorithm**

<table>
<thead>
<tr>
<th>Features</th>
<th>Abbott Freestyle Libre Pro</th>
<th>Dexcom G4 Platinum</th>
<th>Medtronic iPro2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinded or Unblinded</td>
<td>Blinded</td>
<td>Either</td>
<td>Blinded</td>
</tr>
<tr>
<td>Wear Time</td>
<td>14 days</td>
<td>7 days</td>
<td>6 days</td>
</tr>
<tr>
<td>Calibration Required?</td>
<td>0</td>
<td>Twice daily</td>
<td>3-4 times daily</td>
</tr>
<tr>
<td>Components</td>
<td>Disposable combined glucose sensor/transmitter</td>
<td>Disposable wired sensor</td>
<td>Disposable wired sensor</td>
</tr>
<tr>
<td></td>
<td>Separate touchscreen reader device</td>
<td>Data transmitter attached to the sensor</td>
<td>Data transmitter attached to the sensor</td>
</tr>
<tr>
<td>Care Between Use</td>
<td>Disposable sensor/transmitter</td>
<td>Transmitter must be cleaned and disinfected</td>
<td>Transmitter must be cleaned and disinfected</td>
</tr>
<tr>
<td>Insertion</td>
<td>Single step process with auto-inserter</td>
<td>Two-step process which includes inserting sensor and attaching transmitter</td>
<td>Multi-step process which includes inserting and taping both the sensor and transmitter</td>
</tr>
<tr>
<td>Site</td>
<td>Upper Arm</td>
<td>Abdomen</td>
<td>Abdomen</td>
</tr>
<tr>
<td>Downloading/Data Reports</td>
<td>LibreView</td>
<td>Clarity Studio</td>
<td>Carelink</td>
</tr>
</tbody>
</table>

*Continued next page*
Worksheet 7:
Device Choice Algorithm (continued)

Do you want users to be able to wear device longer than 6-7 days?

YES
- Abbott Freestyle Libre Pro

NO
- Dexcom G4 Platinum
- Medtronic iPro 2

Do you want a disposable device or one that can be reused?

Disposable
- Abbott Freestyle Libre Pro

Reused
- Dexcom G4 Platinum
- Medtronic iPro 2

Do you want patients to enter events, such as food and exercise, electronically?

YES
- Dexcom G4 Platinum
- Medtronic iPro 2
- Abbott Freestyle Libre Pro

NO

Do you want the ability to have patients use device data in real time (unblinded) to influence behavior?

YES
- Dexcom G4 Platinum

NO
- Abbott Freestyle Libre Pro
- Medtronic iPro 2
Worksheet 8:  
Inventory Management Protocol

Disposable Devices:
• Order enough so you don’t run out
• Monitor use and order when XX are left. You will be able to soon figure out how many devices are used per month in each program site and keep a month’s supply on hand. You can then order when you get to this number, so you will always have a supply.
• Monitor expiration dates and store product that is expiring sooner in the front
• Make sure there are enough paper logs available to distribute to every patient
• Place a couple of device readers in the clinical area and have some back-ups

Reusable Devices:
• Order enough devices to have on hand
• Monitor warranty periods for the transmitters and order new units before the current ones fall outside of warranty period
• Track devices to ensure that they are returned by the patient in a timely fashion
• Consider having patient sign a contract that they promise to return the transmitter to clinic
• Set up an area in clinic for cleaning and disinfecting the transmitter
• Ensure that staff is following the procedure for cleaning and disinfecting
Worksheet 9:
Sample Protocol – Who Needs Professional CGM

Consider Ordering CGM in the Following Situations:

- Consider Ordering CGM in the Following Situations
- HbA1C greater than 9.0%
- Discordant HbA1C and fingerstick glucose data
- Change in diabetes treatment plan
- Patient has renal impairment
- Patient with frequent hypoglycemia or hypoglycemia unawareness
- Patient with gastroparesis
- Patient does not follow recommendations for checking fingerstick glucose levels
- Annually on patient that is being treated with intensive insulin management plan
- When data is needed to determine Time in Range (TIR)

HbA1C data is collected prior to placement of Professional CGM and again 3 months later.

Sample Documentation

1. Average glucose is 148mg/dL +/-48 BG range: 68-313
2. Total frequency of hypoglycemia: overall 0% BG<70, lowest BG of 68 occurred one time at 7pm
3. Nocturnal hypoglycemia was NOT noted
4. Hyperglycemia episodes: 22% BG>180, post-prandial, often d/t missing prandial insulin, injecting prandial insulin late, or eating high CHO with limited protein.
5. The patient was afraid to inject lispro if BG was in range before meal

++Include AGP or CGM summary with documentation
Worksheet 10: Professional CGM Process Flow

1. Healthcare provider orders Professional CGM

2. Billing team member performs pre-authorization and benefit verification with insurance company

3. Team member that places CGM to instruct individual in details of how to keep the food/med/exercise log while wearing the CGM and stresses importance of this for thorough evaluation purposes

4. Person with diabetes returns to clinic for removal and download of device or mails it back

5. Download and diary sent to ordering provider

6. Device is cleaned and disinfected (if applicable)

7. Provider interprets report, documents in patient record, discusses findings with the person with diabetes (although this is not required for billing) and provides suggestions for any changes to treatment plan

8. Billing process is completed

9. The interpretation, results and any changes to treatment plan are communicated to person with diabetes. You may want to provide a copy of CGM data for the individual.
Worksheet 11: Sample Instructions for Professional CGM for the Person with Diabetes

The purpose of the Professional Continuous Glucose Monitor (CGM) is to assess your blood sugar patterns in response to what you eat, the diabetes medications you take and physical activity. This is why we have you keep a diary of what you eat and when, what time you take your diabetes medications and what activity you do and when, while you are wearing the continuous glucose monitor.

• The continuous glucose monitoring (CGM) device will monitor your blood sugar frequently throughout the day and night.
• Please be sure to record everything that you eat, including portion sizes, all activity you do and when you take your diabetes medication.
• It is okay for you to shower and go about your normal daily activities while wearing the device.
• It is best to wear the device when you are having a normal week and best to avoid if you will be on vacation or undergoing medical testing or procedures.
• At your next scheduled appointment your continuous glucose monitor will be removed, and the data will be evaluated by your health care provider. We will contact you about those results and provide you with next steps, or you may be provided with the option to mail in or drop off your continuous glucose monitor to the clinic.
• If the device falls off before your next appointment is scheduled, simply return the device and your diary to the clinic. If it has been on for greater than three days there might be enough data to complete the test. If it is less than three days, you may need to have another device placed.
“I am not sure how I practiced without CGM.”

- endocrinology provider
Case Study

Patient Profile

Sex/Age: Male, 59 years old
Disease diagnosis: Type 2
HbA1c: 7.9%

Diabetes medication profile: Bi-phasic insulin aspart twice daily, 27 units 07:00 and 19 units at 21:00

Current glucose monitoring: Pre-breakfast, pre-evening meal and occasionally at other times of the day

Rationale for sensor monitoring: Patient has a busy lifestyle which makes regular SMBG testing difficult, particularly when at work; however, he has experienced the “odd” unexpected high reading and would like to know more about what the cause might be.

Baseline Report - Daily Patterns

Glucose Pattern Insights

17 September 2013 - 30 September 2013 (14 days)

LOW-GLUCOSE ALLOWANCE SETTING: Medium
MEDIAN GOAL SETTING: 140 mg/dL (A1c: 6.5% or 48 mmol/mol)

Estimated A1c 7.6% or 60 mmol/mol

VARIABILITY BELOW MEDIAN IS HIGH!

This makes it difficult to achieve the median glucose goal without increasing the likelihood of low glucose.

Factors that could contribute to variability below median:

- Erratic diet
- Incorrect or missed medication
- Alcohol consumption
- Variations in activity level
- Illness

ID: FR-FSL-005-2014. The case study is intended for medical information/education purposes only. It is not intended to be used for medical diagnosis or treatment or as a substitute for professional medical advice. Individual symptoms, situations and circumstances may vary. Information contained herein for distribution outside of the US ONLY. Local legal and regulatory approval is required to publish any content. ADC-02943 v1.0 12/2016
Insights

1. Are the readings within target range (identified target range is 70 – 150mg/dL)? Very few readings are within the range, the majority are above it.

2. What are the patterns of hypoglycemia? There is tendency towards hypoglycemia from waking and particularly during the afternoon to early evening.

3. What is the shape of the median curve? The median curve falls sharply from 08:00 followed by a downward trend with some fluctuations until early evening when it rises sharply before plateauing until 20:00.

4. What is the width of the IQR? The IQR is generally wide, particularly overnight.

5. Where is the risk of hypoglycemia the greatest as indicated by the “likelihood of low glucose” assessment? The risk of overnight hypoglycemia and the time between 12:00-18:00 is of greatest concern.

6. Where is the highest deviation from the median glucose goal indicating the need for greater clinical attention? This occurs between 04:00 and 08:00 where the risk is high. Clinical attention should be focused on this period of the day in order to improve and meet HbA1c targets.

7. Where is the variability below the median greater than a level that would support achieving the median goal without potentially causing low blood glucose? The variability below the median is high from 19:00-08:00. This places the patient at high moderate –high risk of hypoglycemia if factors affecting this variability are not identified and corrected prior to making medication adjustments.
## Actionable Insights

<table>
<thead>
<tr>
<th>Considerations</th>
<th>Next Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target Range</strong></td>
<td>• Review food record keeping and refer to dietitian for food choices and portion sizes and meal pattern.</td>
</tr>
<tr>
<td>• Despite a reasonable HbA1c, only some day time values are within range.</td>
<td>• Observe patient demonstrating pen preparation and injection technique, including correct suspension of the insulin.</td>
</tr>
<tr>
<td>• How often is glucose testing completed during the late afternoon, pre-dinner or at bedtime?</td>
<td>• Discuss any concerns regarding glucose control.</td>
</tr>
<tr>
<td>• What changes does he make as the result of high glucose test results</td>
<td></td>
</tr>
<tr>
<td>• How often are insulin injections missed or delayed and taken after a meal?</td>
<td></td>
</tr>
<tr>
<td>• What concerns or fears does he voice regarding the potential for hypoglycemia during the night?</td>
<td></td>
</tr>
<tr>
<td><strong>Patterns of Hypoglycemia</strong></td>
<td>• Discuss possible causes of variability – including exercise, alcohol, lifestyle, meal pattern.</td>
</tr>
<tr>
<td>• What consistent increase in physical activity is occurring midday that is resulting in lower glucose levels in the later afternoon</td>
<td>• Evaluate his ability to recognize hypoglycemia.</td>
</tr>
<tr>
<td>• How often does insulin stacking occur?</td>
<td>• Review prevention and appropriate treatment of hypoglycemia.</td>
</tr>
<tr>
<td>• Does he inconsistently change the dose of insulin prescribed in response to a high glucose test result?</td>
<td></td>
</tr>
<tr>
<td>• What concerns or fears does he voice regarding the potential for hypoglycemia during the night?</td>
<td></td>
</tr>
<tr>
<td>• What steps are consistently being taken to avoid hypo events overnight that may be contributing too much higher values during the night and upon waking?</td>
<td></td>
</tr>
<tr>
<td><strong>Shape of Median Curve</strong></td>
<td>• Review food records, insulin doses and technique.</td>
</tr>
<tr>
<td>• What type of food choices or other factors are impacting the erratic pattern of the median curve?</td>
<td>• Re-emphasize the need for consistent dosing and timing of insulin injections.</td>
</tr>
<tr>
<td>• What steps are taken to avoid or treat low glucose values?</td>
<td>• Discourage insulin stacking as the result of a high glucose test result.</td>
</tr>
<tr>
<td>• How often is extra insulin taken to correct high glucose levels?</td>
<td></td>
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<tr>
<td>• Does the patient properly suspend the pre-mixed insulin prior to placing it in syringe and injecting?</td>
<td></td>
</tr>
<tr>
<td><strong>Width of IQR</strong></td>
<td>• Education and discussion regarding the impact of food and lifestyle choices on glucose control.</td>
</tr>
<tr>
<td>• What actions are being taken or what food is being consumed that is leading to the pronounced overnight variability?</td>
<td>• Discuss appropriateness of the current insulin regimen relationship to suiting the patient’s lifestyle.</td>
</tr>
<tr>
<td>• Education and discussion regarding the impact of food and lifestyle choices on glucose control.</td>
<td>• Consider insulin pump therapy or multiple daily injections if the current insulin therapy does not meet his lifestyle.</td>
</tr>
</tbody>
</table>
Billy a4 Ocean
DOB: Aug 16, 1980
Overview Report
Generated at: Wed, May 22, 2019 4:02 PM PDT

6.2% 123 57
Glucose Management Indicator
Average glucose (CGM) Standard deviation (CGM) Hypoglycemia risk
6.2% 123 57
mg/dL mg/dL %

Top Patterns

1. Billy had a pattern of nighttime lows
   Billy had a pattern of significant lows between 3:15 AM and 6:00 AM.

2. Billy had a pattern of daytime lows
   Billy had a pattern of significant lows between 8:25 AM and 9:00 AM.

3. Billy had a pattern of nighttime highs
   Billy had a pattern of significant highs between 12:05 AM and 12:45 AM.

This graph shows your data averaged over 14 days.
### Devices

**Dexcom G6 Mobile App**

<table>
<thead>
<tr>
<th>CGM ID</th>
<th>iPhone G6</th>
<th>Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serial Number</td>
<td>Uploaded On</td>
<td>Uploaded On</td>
</tr>
<tr>
<td></td>
<td>May 22, 2019 G6</td>
<td>2019 G6</td>
</tr>
</tbody>
</table>

#### Alert Settings for Device

**General**

- **Low**: Off (75 mg/dL)
- **Low Repeat**: Off (0 min)
- **High**: Off (130 mg/dL)
- **High Repeat**: Off (0 min)
- **Fall Rate**: Off (3 mg/dL/min)
- **Rise Rate**: Off (3 mg/dL/min)
- **Urgent Low**:
  - **Urgent Low Repeat**: On (30 min)
  - **Urgent Low Soon Repeat**: Off (30 min)
  - **Signal Loss**: On (20 min)
1. Billy had a pattern of nighttime lows

Billy had a pattern of significant lows between 3:15 AM and 6:00 AM.

Mon, May 20, 2019

Sat, May 18, 2019

Fri, May 17, 2019

Statistics for these days

<table>
<thead>
<tr>
<th>Date</th>
<th>Average glucose (CGM)</th>
<th>Standard deviation (CGM)</th>
<th>Time in range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mon, May 20, 2019</td>
<td>115 mg/dL</td>
<td>53 mg/dL</td>
<td>17%</td>
</tr>
</tbody>
</table>

Clinician's Notes

Some possible considerations

Consult your Healthcare Professional before making changes.

- Consider adjusting basal insulin.
- Consider adjusting meal-time insulin or bedtime snack.
- Consider effects of evening activity.

Legend

- CALIBRATIONS
- CARBS
- HEALTH
- FAST-ACTING INSULIN
- ALERTS
- LONG-ACTING INSULIN
- EXERCISE
- MULTIPLE EVENTS

What preceded this pattern?

- Insulin
- Meals
- Exercise
- Stress
- Medicine
- Health
**Billy had a pattern of daytime lows**

Billy had a pattern of significant lows between 8:25 AM and 9:00 AM.

### Statistics for these days

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>119</td>
<td>52</td>
</tr>
<tr>
<td>mg/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average glucose (CGM)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>mg/dL</td>
<td>Standard deviation (CGM)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time in range</td>
<td></td>
</tr>
<tr>
<td>21%</td>
<td>46%</td>
<td>31%</td>
</tr>
<tr>
<td></td>
<td>2%</td>
<td></td>
</tr>
</tbody>
</table>

### Clinician’s Notes

Some possible considerations

Consult your Healthcare Professional before making changes.

- Consider adjusting basal insulin.
- Consider adjusting meal-time or correction insulin dose.
- Consider effects of activity or food choices.

### What preceded this pattern?

- Insulin
- Meals
- Exercise
- Stress
- Medicine
- Health
Billy had a pattern of nighttime highs

Billy had a pattern of significant highs between 12:05 AM and 12:45 AM.

Statistics for these days

<table>
<thead>
<tr>
<th>Date</th>
<th>Average glucose (mg/dL)</th>
<th>Standard deviation (mg/dL)</th>
<th>Time in range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wed, May 22, 2019</td>
<td>131</td>
<td>59</td>
<td>27%</td>
</tr>
<tr>
<td>Tue, May 21, 2019</td>
<td>149</td>
<td>35</td>
<td>45%</td>
</tr>
<tr>
<td>Sun, May 19, 2019</td>
<td>120</td>
<td>40</td>
<td>26%</td>
</tr>
</tbody>
</table>

Clinician's Notes

Some possible considerations

Consult your Healthcare Professional before making changes.

- Consider adjusting basal insulin.
- Consider adjusting meal-time, correction, or bed-time snack insulin.
- Consider reviewing the impact of high fat/protein dinner meal.

Legend

- CALIBRATIONS
- CARBS
- HEALTH
- FAST-ACTING INSULIN
- ALTERS
- EXERCISE
- MULTIPLE EVENTS

What preceded this pattern?

- Insulin
- Meals
- Exercise
- Stress
- Medicine
- Health
Billy's best glucose day was May 9, 2019

Billy's glucose data was in the target range about 62% of the day.

**Statistics for this day**

- Average glucose (CGM): 122 mg/dL
- Standard deviation (CGM): 40 mg/dL
- Time in range: 12%

**Clinician's Notes**

What preceded this pattern?

- Insulin
- Meals
- Exercise
- Stress
- Medicine
- Health

**Legend**

- CALIBRATIONS
- CARBS
- HEALTH
- FAST-ACTING INSULIN / INSULIN
- LONG-ACTING INSULIN
- EXERCISE
- MULTIPLE EVENTS
Billy's Overlay View

Week 1

Mon
Tue
Wed
Thu
Fri
Sat
Sun

Thu May 9, 2019 - Wed May 15, 2019

12am 3am 6am 9am 12pm 3pm 6pm 9pm

mg/dL

0 60 100 140 180

Clinician's Notes

Data uploaded: Wed, May 22, 2019 12:24 PM PDT

00386270000491  •  Dexcom CLARITY v3.21.0  •  PN 350-0011  •  DOM 2019-05-02
## Compare Data

### Trends

<table>
<thead>
<tr>
<th>Date Range</th>
<th>Graph 1</th>
<th>Graph 2</th>
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<td>14 days</td>
<td><img src="image1.png" alt="Graph 1" /></td>
<td><img src="image2.png" alt="Graph 2" /></td>
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<td>Thu Apr 25, 2019 - Wed May 8, 2019</td>
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### Glucose Statistics

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<tr>
<td>Standard deviation (CGM)</td>
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Dexcom G4 Platinum

Dexcom and Dexcom CLARITY are registered trademarks of Dexcom, Inc. in the US and may be registered in other countries.
Patterns

**Nighttime Lows**
Billy had a pattern of significant lows between 3:55 AM and 6:00 AM.

**Nighttime Lows**
Billy had a pattern of significant lows between 3:15 AM and 6:00 AM.

**Daytime Lows**
Billy had a pattern of significant lows between 8:00 AM and 8:35 AM.

**Daytime Lows**
Billy had a pattern of significant lows between 8:25 AM and 9:00 AM.

**Best Day**
Billy’s glucose data was in the target range about 74% of the day.

**NEW Nighttime Highs**
Billy had a pattern of significant highs between 12:05 AM and 12:45 AM.

**Best Day**
Billy’s glucose data was in the target range about 62% of the day.
Billy a4 Ocean
DOB: Aug 16, 1980

Compare Report
Generated at: Wed, May 22, 2019 4:02 PM PDT

Devices

14 days | Thu Apr 25, 2019 - Wed May 8, 2019

Dexcom G6 Mobile App

- **Cgm ID**
- **Serial Number**
- **Uploaded On**
- **Model**

- **iPhone G6**
- **May 9, 2019**
- **G6**

14 days | Thu May 9, 2019 - Wed May 22, 2019

Dexcom G6 Mobile App

- **Cgm ID**
- **Serial Number**
- **Uploaded On**
- **Model**

- **iPhone G6**
- **May 22, 2019**
- **G6**

Data uploaded: Wed, May 22, 2019 12:24 PM PDT

Data uploaded: Wed, May 22, 2019 12:24 PM PDT

00386270000491 • Dexcom CLARITY v3.21.0 • PN 350-0011 • DOM 2019-05-02

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### Daily Statistics

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Billy a4 Ocean  
DOB: Aug 16, 1980

Hourly Statistics Report
Generated at: Wed, May 22, 2019 4:02 PM PDT

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Billy a4 Ocean

DOB: Aug 16, 1980

AGP Report

Generated at: Wed, May 22, 2019 4:02 PM PDT

Billy a4 Ocean
Thu May 9, 2019 - Wed May 22, 2019 (13.5 days)

Avg Glucose mg/dL

123

Glucose Exposure

Glucose Statistics

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<th>Glucose Range</th>
<th>Average</th>
<th>Percentage</th>
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</tr>
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<td>Very High</td>
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Glucose Ranges

- Very Low: < 54 mg/dL
- Low: < 70 mg/dL
- In Target Range: 70 - 180 mg/dL
- High: > 180 mg/dL
- Very High: > 250 mg/dL

Coefficient of Variation

46.2%

SD mg/dL

57

% Time CGM Active

97.3%

Data Sufficiency

Glucose Statistics

Ambulatory Glucose Profile

Curves/plots represent glucose frequency distributions by time regardless of date.

The Y axis and target range are the same as on the Ambulatory Glucose Profile graph above.

U.S. Patent No. Des. 773,478, patents pending – HealthPartners Institute dba International Diabetes Center – All Rights Reserved. CapturAGP v. 3.2

Dexcom G4 Platinum

Dexcom and Dexcom CLARITY are registered trademarks of Dexcom, Inc. in the US and may be registered in other countries.
Pattern Snapshot for Sample M. Patient
Sep 28 - Oct 5, 2009
(8 days)

Medtronic iPro2 Recorder
#123456

Avg SG: **119 mg/dL**

Estimated A1C \(^1\): **5.8% (40 mmol/mol)** calculated from SG values

**OBSERVED PATTERNS & SOME POSSIBLE CAUSES \(^2\)**

1. **Variable SG with Low SG**
   - Overnight 23:00 - 6:00
     - 3 day(s) 50 - 80 mg/dL
     - 2 day(s) < 50 mg/dL
     - 3 day(s) > 150 mg/dL

2. **Low SG**
   - Pre-dinner 17:00 - 20:00
     - 2 out of 8 days excursions observed:
       - 2 day(s) 50 - 70 mg/dL
       - 0 day(s) < 50 mg/dL
     - Oral medication(s) too high or incorrectly timed?
     - Basal insulin injection in evening(s) too high or missed?
     - Pre-meal insulin in prior evening(s) incorrectly timed or incorrect dose?
     - Inconsistent food intake day before?
     - Inconsistent exercise schedule day before?
     - Alcohol consumed in prior evening(s)?

3. **High SG**
   - Post-dinner 17:00 - 20:00
     - 2 out of 8 days excursions observed:
       - 0 day(s) 180 - 250 mg/dL
       - 2 day(s) > 250 mg/dL
     - Oral medication(s) missed, too low, or incorrectly timed?
     - Pre-dinner insulin incorrectly timed, too low, or missed?
     - Basal insulin injections too high?
     - Dinner delayed?
     - Exercised before dinner?
     - Insulin to carbohydrate ratio not optimal for pre-dinner insulin?
     - High calorie or high carbohydrate foods?

---

\(^1\) Estimated A1C does not replace Lab measurement and is calculated from limited SG data.

\(^2\) Suggested considerations are limited and do not replace the opinion or advice of the healthcare provider. Please see User Guide on how patterns and possible causes are identified.

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Sensor Data (mg/dL)  A thicker flat sensor trace at 40 or 400 mg/dL indicates CGM values can be outside these limits.

Excursion Summary (mg/dL/day)

Duration Distribution (hh:mm)
Overlay by Meal for Sample M. Patient
Sep 28 - Oct 5, 2009
(8 days)
Medtronic iPro2 Recorder
#123456

Overlay by Meal Event (mg/dL)

<table>
<thead>
<tr>
<th>Meal Event</th>
<th>Before Breakfast</th>
<th>After Breakfast</th>
<th>Before Lunch</th>
<th>After Lunch</th>
<th>Before Dinner</th>
<th>After Dinner</th>
<th>Evening 23:00 - 3:00</th>
<th>All Time Periods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleeping 3:00 - 6:00</td>
<td>80 - 150</td>
<td>70 - 180</td>
<td>70 - 150</td>
<td>70 - 180</td>
<td>70 - 150</td>
<td>70 - 180</td>
<td>80 - 150</td>
<td></td>
</tr>
<tr>
<td>Highest</td>
<td>174</td>
<td>185</td>
<td>181</td>
<td>178</td>
<td>241</td>
<td>101</td>
<td>268</td>
<td>158</td>
</tr>
<tr>
<td>Lowest</td>
<td>41</td>
<td>47</td>
<td>62</td>
<td>71</td>
<td>72</td>
<td>59</td>
<td>112</td>
<td>40</td>
</tr>
<tr>
<td>Average</td>
<td>96</td>
<td>107</td>
<td>114</td>
<td>112</td>
<td>148</td>
<td>78</td>
<td>185</td>
<td>94</td>
</tr>
<tr>
<td>Standard Dev.</td>
<td>29</td>
<td>46</td>
<td>31</td>
<td>30</td>
<td>49</td>
<td>11</td>
<td>50</td>
<td>24</td>
</tr>
<tr>
<td># of Readings</td>
<td>252</td>
<td>36</td>
<td>72</td>
<td>84</td>
<td>168</td>
<td>36</td>
<td>72</td>
<td>336</td>
</tr>
</tbody>
</table>

Daily Average by Meal Event (mg/dL)

<table>
<thead>
<tr>
<th>Meal Event</th>
<th>Before Breakfast</th>
<th>After Breakfast</th>
<th>Before Lunch</th>
<th>After Lunch</th>
<th>Before Dinner</th>
<th>After Dinner</th>
<th>Evening 23:00 - 3:00</th>
<th>All Time Periods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleeping</td>
<td>143</td>
<td>175</td>
<td>72</td>
<td>213</td>
<td>61</td>
<td>123</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tue Sep 29</td>
<td>136</td>
<td>197</td>
<td>90</td>
<td>217</td>
<td>127</td>
<td>134</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wed Sep 30</td>
<td>110</td>
<td>143</td>
<td>140</td>
<td>85</td>
<td>109</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thu Oct 1</td>
<td>81</td>
<td>118</td>
<td>141</td>
<td>100</td>
<td>104</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fri Oct 2</td>
<td>98</td>
<td>75</td>
<td>167</td>
<td>92</td>
<td>107</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sat Oct 3</td>
<td>108</td>
<td>99</td>
<td>83</td>
<td>91</td>
<td>97</td>
<td>70</td>
<td>126</td>
<td>90</td>
</tr>
<tr>
<td>Sun Oct 4</td>
<td>83</td>
<td>56</td>
<td>110</td>
<td>79</td>
<td>116</td>
<td>104</td>
<td>96</td>
<td></td>
</tr>
<tr>
<td>Mon Oct 5</td>
<td>134</td>
<td>166</td>
<td>151</td>
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</tbody>
</table>

Duration Distribution (hh:mm)

<table>
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<tr>
<th>Duration Distribution (hh:mm)</th>
<th>Sleeping</th>
<th>Before Breakfast</th>
<th>After Breakfast</th>
<th>Before Lunch</th>
<th>After Lunch</th>
<th>Before Dinner</th>
<th>After Dinner</th>
<th>Evening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Above</td>
<td>1:20</td>
<td>6%</td>
<td>0:55</td>
<td>31%</td>
<td>0:05</td>
<td>1%</td>
<td>0:35</td>
<td>8%</td>
</tr>
<tr>
<td>In Range</td>
<td>13:20</td>
<td>64%</td>
<td>1:05</td>
<td>36%</td>
<td>5:30</td>
<td>92%</td>
<td>6:25</td>
<td>92%</td>
</tr>
<tr>
<td>Below</td>
<td>6:20</td>
<td>30%</td>
<td>1:00</td>
<td>33%</td>
<td>0:25</td>
<td>7%</td>
<td>0:00</td>
<td>0%</td>
</tr>
</tbody>
</table>

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Night Time Sensor Data (mg/dL)

<table>
<thead>
<tr>
<th>Mon Sep 28</th>
<th>Tue Sep 29</th>
<th>Wed Sep 30</th>
<th>Thu Oct 1</th>
<th>Fri Oct 2</th>
<th>Sat Oct 3</th>
<th>Sun Oct 4</th>
<th>Mon Oct 5</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

![Graph showing night time sensor data (mg/dL) from Mon Sep 28 to Mon Oct 5.](image)

Notes:
A thicker flat sensor trace at 40 or 400 mg/dL indicates CGM values can be outside these limits.
A thicker flat sensor trace at 40 or 400 mg/dL indicates CGM values can be outside these limits.
## Patient Notes for Sample M. Patient
### Sep 28 - Oct 5, 2009

<table>
<thead>
<tr>
<th>Date and Time</th>
<th>Event</th>
<th>Event Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>0:00:00</td>
<td>Note</td>
<td>Toujeo....</td>
</tr>
<tr>
<td>7:02:00</td>
<td>BG</td>
<td>130 mg/dL</td>
</tr>
<tr>
<td>11:25:00</td>
<td>Meal</td>
<td>Unknown size</td>
</tr>
<tr>
<td></td>
<td>BG</td>
<td>100 mg/dL</td>
</tr>
<tr>
<td>17:53:00</td>
<td>Meal</td>
<td>Unknown size</td>
</tr>
<tr>
<td></td>
<td>BG</td>
<td>72 mg/dL</td>
</tr>
<tr>
<td>18:31:00</td>
<td>BG</td>
<td>30 mg/dL</td>
</tr>
<tr>
<td>20:49:00</td>
<td>Medication</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BG</td>
<td>214 mg/dL</td>
</tr>
<tr>
<td>5:19:00</td>
<td>Meal</td>
<td>Unknown size</td>
</tr>
<tr>
<td></td>
<td>BG</td>
<td>30 mg/dL</td>
</tr>
<tr>
<td>11:47:00</td>
<td>Meal</td>
<td>Unknown size</td>
</tr>
<tr>
<td></td>
<td>BG</td>
<td>142 mg/dL</td>
</tr>
<tr>
<td>13:13:00</td>
<td>BG</td>
<td>204 mg/dL</td>
</tr>
<tr>
<td>19:15:00</td>
<td>Meal</td>
<td>Unknown size</td>
</tr>
<tr>
<td></td>
<td>BG</td>
<td>100 mg/dL</td>
</tr>
<tr>
<td>21:05:00</td>
<td>BG</td>
<td>240 mg/dL</td>
</tr>
<tr>
<td>7:43:00</td>
<td>Exercise</td>
<td>Unknown intensity</td>
</tr>
<tr>
<td></td>
<td>BG</td>
<td>126 mg/dL</td>
</tr>
<tr>
<td>8:21:00</td>
<td>BG</td>
<td>150 mg/dL</td>
</tr>
<tr>
<td>11:30:00</td>
<td>Meal</td>
<td>Unknown size</td>
</tr>
<tr>
<td></td>
<td>BG</td>
<td>150 mg/dL</td>
</tr>
<tr>
<td>16:43:00</td>
<td>Meal</td>
<td>Unknown size</td>
</tr>
<tr>
<td></td>
<td>BG</td>
<td>104 mg/dL</td>
</tr>
<tr>
<td>21:28:00</td>
<td>BG</td>
<td>76 mg/dL</td>
</tr>
<tr>
<td>4:20:00</td>
<td>BG</td>
<td>82 mg/dL</td>
</tr>
<tr>
<td>12:27:00</td>
<td>Meal</td>
<td>Unknown size</td>
</tr>
<tr>
<td></td>
<td>BG</td>
<td>116 mg/dL</td>
</tr>
<tr>
<td>18:28:00</td>
<td>BG</td>
<td>90 mg/dL</td>
</tr>
<tr>
<td>7:10:00</td>
<td>BG</td>
<td>118 mg/dL</td>
</tr>
<tr>
<td>11:55:00</td>
<td>Meal</td>
<td>Unknown size</td>
</tr>
<tr>
<td></td>
<td>BG</td>
<td>70 mg/dL</td>
</tr>
<tr>
<td>15:50:00</td>
<td>BG</td>
<td>94 mg/dL</td>
</tr>
<tr>
<td>18:08:00</td>
<td>BG</td>
<td>122 mg/dL</td>
</tr>
<tr>
<td>Date and Time</td>
<td>Event Details</td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>---------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Saturday October 3, 2009</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7:15:00</td>
<td>Meal Unknown size</td>
<td>BG 106 mg/dL</td>
</tr>
<tr>
<td>10:45:00</td>
<td>BG 80 mg/dL</td>
<td></td>
</tr>
<tr>
<td>12:10:00</td>
<td>Meal Unknown size</td>
<td>BG 100 mg/dL</td>
</tr>
<tr>
<td>14:26:00</td>
<td>Exercise Unknown intensity</td>
<td>BG 112 mg/dL</td>
</tr>
<tr>
<td>17:31:00</td>
<td>Meal Unknown size</td>
<td>BG 84 mg/dL</td>
</tr>
<tr>
<td><strong>Sunday October 4, 2009</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8:18:00</td>
<td>Meal Unknown size</td>
<td>BG 60 mg/dL</td>
</tr>
<tr>
<td>12:16:00</td>
<td>Meal Unknown size</td>
<td>BG 80 mg/dL</td>
</tr>
<tr>
<td>17:54:00</td>
<td>BG 84 mg/dL</td>
<td></td>
</tr>
<tr>
<td>20:59:00</td>
<td>BG 174 mg/dL</td>
<td></td>
</tr>
<tr>
<td><strong>Monday October 5, 2009</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5:55:00</td>
<td>BG 158 mg/dL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medication</td>
<td></td>
</tr>
<tr>
<td>7:20:00</td>
<td>Meal Unknown size</td>
<td>BG 166 mg/dL</td>
</tr>
<tr>
<td>10:26:00</td>
<td>BG 166 mg/dL</td>
<td></td>
</tr>
<tr>
<td>13:59:00</td>
<td>BG 190 mg/dL</td>
<td></td>
</tr>
<tr>
<td>16:14:00</td>
<td>BG 70 mg/dL</td>
<td></td>
</tr>
</tbody>
</table>
PART FIVE: Resources & Research List

RESOURCES: MANUFACTURER SUPPLIED
ONLINE TRAINING/TUTORIALS

- Abbott Tutorials [CLICK HERE]
- Dexcom Tutorials [CLICK HERE]
- Medtronic Tutorials [CLICK HERE]

RESOURCES: danatech product specs and online learning

AADE danatech - www.danatech.org

danatech includes access to CGM device information, including technical specs and resources for diabetes educators, providers and people with diabetes. Free subscription access is available to AADE and National Association of School Nurses (NASN) Members.

Free online CGM CE Courses available to AADE and NASN members. Requires username and password.
- Continuous Glucose Monitoring: Connecting the Dots – 5 CE Hours
- Continuous Glucose Monitoring: Real World Case Studies in Pattern Management – 4.5 CE Hours
- CGM Data in Clinical Practice – 1.5 CE Hours
- The Ins and Outs of Starting a CGM Program – 1.50 CE Hours
RESEARCH AND RESOURCES


Carlson AL, Mullen DM, Bergenstal RM. Clinical Use of Continuous Glucose Monitoring in Adults with Type 2 Diabetes. Diabetes Technology & Therapeutics. 2017;19:S4–11


Lu B, Goldman JD. Glucose Variability and the Use of Continuous Glucose Monitors in People with Type 1 and Type 2 Diabetes. AADE in Practice. 2018;6(6):22-25

Medtronic. Professional CGM Reimbursement Guide. 2018


AADE and AANP

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