REAL-TIME
CONTINUOUS GLUCOSE MONITORING:
TECHNOLOGY TO HELP
YOUR PRACTICE AND PATIENTS

August 8, 2013
Welcome and Introductions

Keri Weindel, MS, RD, CDE
Director, Professional Education
Dexcom, Inc.
# Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter/Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:15 PM</td>
<td>Doors Open and Refreshments Served</td>
<td></td>
</tr>
<tr>
<td>2:15 PM</td>
<td><strong>Hands-on Demonstrations of Dexcom G4® Platinum CGM System</strong></td>
<td>Demonstration Booths</td>
</tr>
<tr>
<td></td>
<td><strong>Dexcom Studio™ Software</strong></td>
<td></td>
</tr>
<tr>
<td>2:45 PM</td>
<td><strong>Welcome and Introductions</strong></td>
<td>Keri Weindel, MS, RD, CDE</td>
</tr>
<tr>
<td></td>
<td>• Program Objectives</td>
<td></td>
</tr>
<tr>
<td>2:50 PM</td>
<td><strong>Practical Application of CGM in Clinical Practice: Patient</strong></td>
<td>Gregg F. Gerety, MD</td>
</tr>
<tr>
<td></td>
<td><strong>Selection and Real-time use</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Audience Response</td>
<td></td>
</tr>
<tr>
<td>3:25 PM</td>
<td><strong>CGM Reimbursement for Your Practice and Patients</strong></td>
<td>Patty Curoe Telgener, MBA, RN</td>
</tr>
<tr>
<td></td>
<td>• Audience Response</td>
<td></td>
</tr>
<tr>
<td>3:45 PM</td>
<td><strong>Questions and Answers</strong></td>
<td></td>
</tr>
<tr>
<td>4:00 PM</td>
<td><strong>Adjourn</strong></td>
<td>Dr. Gerety and Ms. Telgener are available at this time to address any additional</td>
</tr>
<tr>
<td></td>
<td></td>
<td>questions you may have at the <strong>Dexcom Booth #1401</strong></td>
</tr>
</tbody>
</table>
Practical Application of CGM in Clinical Practice:

Patient Selection and Real-Time Use

Gregg F. Gerety, MD
Endocrinologist
The Endocrine Group
Albany, NY
Disclosures

• Research Contracts: NovoNordisk, Eli Lilly
• Consultant/Speaker Bureaus: Dexcom, Inc., SIGMA – CGM Advocacy Group sponsored by Dexcom, NovoNordisk, Eli Lilly, Boehringer-Ingelheim, Astra Zeneca
CGM Use in My Practice

Personal CGM Use

Professional CGM Use

Remember, your healthcare professional and Medtronic are here to support you every step of the way.

CGM Reimbursement for training and interpretation
Why Is Real Time CGM Needed?

• GET HBA1C TO PERSONAL GOAL
• MINIMIZE/AVOID SIGNIFICANT HYPERGLYCEMIA, VARIABILITY
• MINIMIZE/AVOID HYPOGLYCEMIA
• DIAGNOSE GLUCOSE PATTERNS & TRIAL REAL-TIME CGM WITH PROFESSIONAL USE
KNOW YOUR NUMBER!

INCREASED FINGERSTICK GLUCOSE TESTING CORRELATES WITH LOWER HBA1C
Evidence of a Strong Association Between Frequency of Self-Monitoring of Blood Glucose and Hemoglobin A1C Levels in T1D Exchange Clinic Registry Participants

Kellee M. Miller, mph²
Roy W. Beck, md, PhD²
Richard M. Bergenstal, md²
Robin S. Goland, md³
Michael J. Haller, md⁴

Janet B. McGill, md⁵
Henry Rodriguez, md⁶
Jill H. Simmons, md⁷
Irl B. Hirsch, md⁸
For the T1D Exchange Clinic Network

State Healthcare Authority questioned whether sufficient evidence is available to justify unlimited coverage of SMBG test strips for patients with type 1 diabetes (6).

The large database of the T1D Ex-
Higher Frequency of SMBG Led to Lower A1C Based T1D Exchange Registry
SEEING IS BELIEVING!

REGULAR SENSOR USE CORRELATES WITH LOWER HBA1C AND LESS HYPOGLYCEMIA

The NEW ENGLAND JOURNAL of MEDICINE

Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes

The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group
Real Time CGM Use Led to Reduction in HbA1c at 6 Months Through 18 Months for Patient with >7% HbA1c

The Reduction In A1c Is Directly Correlated with Frequency of Sensor Use

---


---

Pediatrics, Adolescents and Adults with >7% A1c Showed Reduction of A1c with Frequency of CGM Use (≥6 day/week) at 12 Months

Change in A1c (%)

Age > 25  
N=34  
-0.5

Age 15-24  
N=6  
-0.5

Age 8-14  
N=15  
-0.7 -0.8 -1.0

Diabetes Care 2009; 32:2047-2049

Real Time CGM Showed Consistent Reduction of A1c Without Increased Hypoglycemia for ≤7% Subgroup

*Error bars show the 95% confidence interval (CI).

Diabetes Care 2009: 32:1378-1383
Time Spent in Hypoglycemia Significantly Reduced with CGM

Frequency of CGM Glucose Levels ≤ 70, ≤ 60 and ≤ 50 mg/dL

Each comparison Baseline vs 13 and 26 wks

Diabetes Care 2009: 32:1378-1383
Two Eras of Diabetes Management

Rate of severe Hypoglycemia (per 100 patient-years)

DCCT: 1986 to 1993

JDRF CGM Study

Control Group 2006-2007

Glycosylated Hemoglobin (%)

DCCT. N Engl J Med 1993;329:977-86
Impact of CGM on Rate of Severe Hypoglycemia Compared to DCCT
Patient Selection For Real Time CGM

- T1DM & T2DM ON INSULIN
- ELEVATED HBA1C
- NORMAL HBA1C
- HYPOGLYCEMIA
- FAVORABLE RESPONSE TO TRIAL
Patient Persistence of CGM Use in A Clinical Practice – Salt Lake City, Utah

Exactly one year after starting your CGM system, how often were you wearing it?

<table>
<thead>
<tr>
<th></th>
<th>Almost Daily</th>
<th>3 Weeks/Month</th>
<th>2 Weeks/Month</th>
<th>1 week or Less/Month</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medtronic MiniLink (n=43)</strong></td>
<td>8 (19%)</td>
<td>6 (14%)</td>
<td>1 (2%)</td>
<td>28 (65%)</td>
</tr>
<tr>
<td><strong>Dexcom SEVEN PLUS (n=38)</strong></td>
<td>29 (76%)</td>
<td>3 (8%)</td>
<td>5 (13%)</td>
<td>1 (3%)</td>
</tr>
</tbody>
</table>

Patient Persistence of CGM Use in A Clinical Practice – Salt Lake City, Utah

Would you purchase the same system again if given the chance?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic MiniLink (n=43)</td>
<td>19 (44%)</td>
<td>24 (56%)</td>
</tr>
<tr>
<td>Dexcom SEVEN PLUS (n=38)</td>
<td>35 (92%)</td>
<td>3 (7%)</td>
</tr>
</tbody>
</table>

Would you try another system if given the chance?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic MiniLink (n=43)</td>
<td>19 (44%)</td>
<td>24 (56%)</td>
</tr>
<tr>
<td>Dexcom SEVEN PLUS (n=38)</td>
<td>9 (16%)</td>
<td>28 (74%)</td>
</tr>
</tbody>
</table>

SIMPLIFYING CGM INTERPRETATION AND PATTERN MANAGEMENT WITH DEXCOM STUDIO SOFTWARE – REVIEW OF PATIENT CASE STUDIES
CGM Interpretation – Stepwise Approach

1. Hypoglycemia
   – Nocturnal
   – During Day
2. Overnight control/fasting glucose
   – Look to dinner for potential causes of overnight control issues
3. Pre-meal control
4. Post-meal control
5. Lifestyle

Remember the importance of interviewing your patients…!
Case Study #1

Pattern Insights Summary

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Insights</th>
<th>Some Possible Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daytime Lows</td>
<td>(0 Found)</td>
<td>No significant patterns detected</td>
</tr>
<tr>
<td>Nighttime Lows</td>
<td>(0 Found)</td>
<td>No significant patterns detected</td>
</tr>
<tr>
<td>Daytime Highs</td>
<td>(2 Found)</td>
<td>Most significant pattern of highs found between 8:15 PM and 4:10 PM</td>
</tr>
</tbody>
</table>
Hello, Dr. Gerety!!
This is Kathy.

I was in the office on 3/22/2013 to get my Dexcom, and is it ok to tell you that I love it? This is so amazing to me. It hasn't been 24 hours yet, and I don't want to give it back!! But, I will. Thank you for recommending this awesome machine.

Kathy,

Your recent recent 7 day Dexcom sensor download (3/22-3/28/13) attached above shows avg. sensor glucose 243mg/dl w/ 12% in 80-130 target, 1% in low range, 39-79 and 87% in high range 131-401. Trend analysis shows high between 9 pm till 4 pm. Your current insulin regimen is 55 u Levemir in AM and 20 u in PM; Novolog 15u BRK, 6-10u LUN, 8-10 u DIN. My advice is to raise Levemir dose from 20 to 32 units every pm & continue 55 units every am. I'm also advising Novolog dose change to 20-6-14 units w/ B-L-D, respectively. Please send me new diabetes eelog or glucose log to review in 1 week. - G. Gerety, MD
**Case Study #2**

### Pattern Insights Summary

<table>
<thead>
<tr>
<th></th>
<th>Some Possible Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nighttime Lows</strong> (0 Found)</td>
<td>No significant patterns detected</td>
</tr>
<tr>
<td><strong>Daytime Lows</strong> (0 Found)</td>
<td>No significant patterns detected</td>
</tr>
<tr>
<td><strong>Nighttime Highs</strong> (0 Found)</td>
<td>No significant patterns detected</td>
</tr>
<tr>
<td><strong>Daytime Highs</strong> (0 Found)</td>
<td>No significant patterns detected</td>
</tr>
</tbody>
</table>

**Statistics**

- Average Glucose: 126 mg/dL
- Sensor Usage: 6 of 14 Days
- Calibrations / day: 5.0
- Standard Deviation: ± 28 mg/dL

**Target Range**: 80 - 140 mg/dL

**Nighttime**: 10:00 PM - 6:00 AM

---

*Note: See above graph for other patterns as well as review any individualized considerations.*
Paul,

• This recent 6 day (6/21 – 6/26/13) Dexcom sensor download shows avg. sensor glucose 126 mg/dl w/ 73% in 80-140 target, 2% in low range, 39-79 and 25% in high range 141-401. Excellent!

• This while on HUMULIN R U-500 (CONCENTRATED) 500UNIT/ML SOLN 10,5-10,10-15U TID W/ B,L,D. Trend analysis shows small bump up, 150-200, after breakfast & less so, but on occasion, following dinner.

• You can try moving your Humulin R U-500 shot back to 30 minutes before breakfast meal. If this doesn’t improve post-breakfast bump up, then we may consider small dose increase from 10 to 11 units before breakfast.

• Would you like to have your own personal sensor for daily use? Keep up the excellent work. No other changes advised. - G. Gerety, MD
Dr. Gregg,

• Thank you for the meter results, and the opportunity to have one for my daily use.

• And yes, I believe the Dexcom meter helped out, at the least, I had "peace of mind" during the evening sleep periods. Also, having the meter I was able to see the BG trends during the day, which helps pinpoint the time of day I need to watch as trouble times.

• Trying to diet and having diabetes is a challenge, you're numbers vary as you try to adjust the amount of insulin you take, the meter is a definite plus in this area.

• The icon arrow and graph kept me informed totally, even though the BG number could be off (learned to utilize the trends). I would definitely recommend one for myself. Would love one...
### Pattern Insights Summary

<table>
<thead>
<tr>
<th>Pattern Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nighttime Lows</td>
<td>(0 Found) No significant patterns detected</td>
</tr>
<tr>
<td>Daytime Lows</td>
<td>(0 Found) No significant patterns detected</td>
</tr>
<tr>
<td>Nighttime Highs</td>
<td>(0 Found) No significant patterns detected</td>
</tr>
<tr>
<td>Daytime Highs</td>
<td>(1 Found) Most significant pattern of highs found between 11:25 AM and 7:55 AM</td>
</tr>
</tbody>
</table>

### Some Possible Considerations

- Adjustment to the timing of insulin delivery
- Adjustment to meal-time insulin or correction dose
- Effects of exercise, alcohol, and/or food choices

### Statistics

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Glucose</td>
<td>202 mg/dL</td>
</tr>
<tr>
<td>Sensor Usage</td>
<td>7 of 7 Days</td>
</tr>
<tr>
<td>Calibrations / day</td>
<td>5.4</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>± 71 mg/dL</td>
</tr>
<tr>
<td>Target Range</td>
<td>80 - 140 mg/dL</td>
</tr>
<tr>
<td>Nighttime</td>
<td>10:00 PM - 6:00 AM</td>
</tr>
</tbody>
</table>
Patricia,

- Your recent 7 day Dexcom sensor download (5/11 – 5/17/13) shows avg. sensor glucose 202mg/dl w/ 20% in 80-140 target, 1% in low range, 39-79 and 79% in high range 141-401.
- Trend analysis shows most pronounced high between 11:30 am throughout remainder of day & overnight until 8 am. My advice is to increase each Levemir shot by 2 units, (22 to 24 units q noon & from 20 to 22 units every bedtime).
- You would also likely benefit from taking 12+ units of Humalog 15-30 minutes before each meal if fingerstick glucose & food intake normal/routine, but more if either high glucose or increased food intake.
- Please make these small changes & send new glucose log in 1 week. Did you find sensor use helpful? Would you like to have your own sensor for personal, daily use? G. Gerety, MD

Hi Dr. Gerety, I LOVED having the Dexcom sensor! It went off quite a few times at 80, especially in the AM before I woke up! this saved me from having a reaction, and will at some point save my life as I have no feelings of high or low- esp. low!!!! I loved being able to just push a button and read my BS anytime, anywhere. I just have to have one! I know you said you would fight for me,
Patient Communication and Assessment – Case Study #4

- 54 YOWM
- T2DM X 20 YR, HBP, LIPIDS
- INSULIN PUMP X 2 YR

<table>
<thead>
<tr>
<th>Time</th>
<th>Rate (u/hr)</th>
<th>CHO Ratio: 1u:7@24; 1u:5@11</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>2.2</td>
<td>Sensitivity Ratio: 1u:25</td>
</tr>
<tr>
<td>04</td>
<td>1.9</td>
<td>Target Glucose: 90-120</td>
</tr>
<tr>
<td>12</td>
<td>1.7</td>
<td>Insulin Duration: 3 hr</td>
</tr>
<tr>
<td>21</td>
<td>2.2</td>
<td></td>
</tr>
</tbody>
</table>

- PHYSICALLY ACTIVE, HYPOGLYCEMIA,
- HBA1C 7.81 (3/2011, PRE-PUMP ON MDI)
Case Study #4

Pattern Insights Summary

<table>
<thead>
<tr>
<th>Nighttime Lows (0 Found)</th>
<th>No significant patterns detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daytime Lows (0 Found)</td>
<td>No significant patterns detected</td>
</tr>
<tr>
<td>Nighttime Highs (0 Found)</td>
<td>No significant patterns detected</td>
</tr>
<tr>
<td>Daytime Highs (0 Found)</td>
<td>No significant patterns detected</td>
</tr>
</tbody>
</table>

Note: See above graph for other patterns as well as review any individualized considerations.

Statistics

- Average Glucose: 158 mg/dL
- Sensor Usage: 12 of 14 Days
- Calibrations / day: 1.8
- Standard Deviation: ± 49 mg/dL
- 68% High
- 30% Target
- 2% Low
- Target Range: 80 - 130 mg/dL
- Nighttime: 10:00 PM - 6:00 AM

Interpretation

The glucose levels show variability throughout the day with high deviations. The graph highlights periods of high glucose levels, particularly around May 30th. The standard deviation indicates significant variability. No specific patterns are noted for nighttime or daytime high or low glucose levels. Further individualized considerations are recommended for a more comprehensive analysis.
The patient does not present written record of fingersticks for analysis.

But his recent 12 day Dexcom sensor download (5/29 - 6/11/13) shows avg. sensor glucose 158mg/dl w/ 30% in 80-130 target, 2% in low range, 39-79 and 68% in high range 131-401.

Trend analysis shows upward trend following dinner on 3-4 nights & high trend 150-250 between 24 - 06 on 5/12 days.

Lows below 80 were isolated, sporadic & infrequent.

The patient's medical regimen as it pertains to the diabetes mellitus will remain unchanged at this point.

He was advised to minimize food grazing activity following dinner which may be contributing to high pattern noted above.
### Patient Communication and Assessment – Case Study #4

<table>
<thead>
<tr>
<th></th>
<th>03/2011</th>
<th>06/2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated Avg Glucose</td>
<td>177 mg/dl</td>
<td>154 mg/dl</td>
</tr>
<tr>
<td>A1c</td>
<td>7.81%</td>
<td>6.99%</td>
</tr>
<tr>
<td>Glucose</td>
<td>286 mg/dl</td>
<td>276 mg/dl</td>
</tr>
</tbody>
</table>
WHERE DO WE GO FROM HERE?
Boston Bionic Pancreas

Dexcom G4 receiver + insulin control algorithms connected to the back of a cell phone (all-in-one system).

What Is the Bionic Pancreas?

- One of the first home use artificial pancreas studies
- Based on weight initially
- Device has Dexcom G4 CGM technology with insulin controllers for basal, bolus and pre-meal priming and one glucagon controller
- Predicts pending insulin action based on models for insulin absorption and clearance

Bionic Pancreas Studies Going On Right Now

Beacon Hill (on going)

- 20 adults ≥21 years old
- CL vs. OL crossover study for 5 days
- “Real life living” in downtown Boston, access to gym, sleep at hotel where they can be monitored
- 2400 hours closed-loop

Diabetes Camp (07-08, 2013)

- 36 children 12-20 years old
- CL vs. OL crossover study for 5 days
- Full access to ‘real life camping’ and activities
- SMBG 8x/day
- RN supervision
- 24 hour telemetry
- 4320 hours closed-loop

Initial Results of Five Days of Beacon Hill/Bionic Pancreas Study

Usual Care – CSII + CGM

- CGM (N=439, 127±55 mg/dL, [30.9, 310]), 71.1% <80 mg/dL, 15.6% <70 mg/dL, 7.1% in 70-180 mg/dL, MAE=11.5%
- BS (N=3, [43, 233])

11.5% Sensor Error (MARD)

Bionic Pancreas – Full Closed Loop Control with CSII + CGM + Control Algorithm

- CGM (N=1426, 172±71 mg/dL, [51, 203]), 3.5% <60 mg/dL, 3.8% <70 mg/dL, 96% in 70-180 mg/dL, MAE=12.3%
- BS (N=45, 120±24 mg/dL, A1c = 5.8%, [76, 199], 0.0% <60 mg/dL, 0.0% <70 mg/dL, 98% in 70-180 mg/dL)

12.3% Sensor Error (MARD)
Preliminary Results of First 5 Days of Beacon Hill Adult Bionic Pancreas Study

<table>
<thead>
<tr>
<th>Subject</th>
<th>CGM average (mg/dl)</th>
<th>BG average (mg/dl) [Projected A1c (%)]</th>
<th>% BG values &lt; 60 mg/dl</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Days 2 &amp; 3</td>
<td>Days 4 &amp; 5</td>
<td>Days 2 &amp; 3</td>
</tr>
<tr>
<td>Subject B01</td>
<td>109</td>
<td>110</td>
<td>116</td>
</tr>
<tr>
<td>Subject B05</td>
<td>124</td>
<td>130</td>
<td>126</td>
</tr>
<tr>
<td>Subject B07</td>
<td>132</td>
<td>114</td>
<td>133</td>
</tr>
<tr>
<td>Subject B09</td>
<td>130</td>
<td>129</td>
<td>143</td>
</tr>
<tr>
<td>Subject B14</td>
<td>129</td>
<td>122</td>
<td>121</td>
</tr>
<tr>
<td><strong>Average ± SD</strong></td>
<td><strong>124 ± 9</strong></td>
<td><strong>121 ± 9</strong></td>
<td><strong>128 ± 11</strong></td>
</tr>
</tbody>
</table>

CGM Future is Bright…

But the Future is NOW with a Technology That Can Help Your Patients Today!
CGM Reimbursement for Your Practice and Patients

Patty Curoe Telgener RN, MBA
VP of Reimbursement
Emerson Consultants
Reimbursement is the interaction of these separate, yet distinct aspects of the healthcare system.

Coding, Coverage and Payment are already established for CGM.
Professional vs. Personal Use CGM

- **Professional use devices** are owned and operated by the physician office
  - Generally used for “short term” monitoring
  - Can be a “blinded device” or “real-time”
  - CPT codes exist for billing of services
  - Providers may need to check with payer for prior auth (differs by payer)
  - There is Medicare payment for CGM (professional use)
  - CPT codes exist for billing of services

- **Personal/Patient use devices** are owned by the patient
  - Generally fall under the “long term” use category
  - Usually processed as a DME product, using HCPCS codes
  - DexCom does the insurance processing – nearly all commercial plans now cover CGM devices if patient meets criteria
  - Medicare does not cover the purchase of the device
  - Providers can use CPT codes for training and interpretation of downloads (always need to check with payer for specifics)
CGM CPT Codes

• 95250: Ambulatory continuous glucose monitoring of interstitial fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording.

[Do not report more than once per month]*

• 95251: Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report.

[Do not report more than once per month]*
## Who Can Bill For CGM?

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Perform Service</th>
<th>Bill Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>95250</td>
<td>RN, CDE, RD, PharmD, MD, NP, PA and possibly MA depending on scope of practice</td>
<td>MD, NP, PA and diabetes center</td>
</tr>
<tr>
<td>95251</td>
<td>MD, NP and/or PA</td>
<td>MD, NP and/or PA</td>
</tr>
</tbody>
</table>

Do not need to be ADA or AADE accredited to bill for CGM
## CGM Payment Level

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Payment*</th>
</tr>
</thead>
<tbody>
<tr>
<td>95250</td>
<td>Professional CGM: • Pt training; hookup, removal, download</td>
<td>2013 National Medicare Physician Fee Schedule = $166 (varies by state)</td>
</tr>
<tr>
<td></td>
<td>Patient CGM: • First time training/setup</td>
<td>Medicare payment in Diabetes Center (APC 0607) $97</td>
</tr>
<tr>
<td>95251</td>
<td>Professional CGM: • Interpretation of data report • Can be non face to face • Billed no more than once a month</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient CGM: • Interpretation of data report • Can be non face to face • Billed no more than once a month</td>
<td>2013 National Medicare Average = $43 (varies by state)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medicare does not pay for Patient/Personal use CGM</td>
</tr>
</tbody>
</table>
# CGM Reimbursement Compared to Other DSMT Services

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Physician Office (performed by RN or CDE)</th>
<th>Diabetes Center (performed by RN or CDE)</th>
<th>Physician Office (performed by MD,NP,PA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation and Management (E/M) (Established patient: 99211-99215)</td>
<td>$20 (99211 only)</td>
<td>N/A</td>
<td>$43-$140</td>
</tr>
<tr>
<td>G-codes (G0108)</td>
<td>$53 (only if accredited)</td>
<td>$53 (only if accredited)</td>
<td>$53 (only if accredited)</td>
</tr>
<tr>
<td>95250</td>
<td>$166 †</td>
<td>$97†</td>
<td>$166 †</td>
</tr>
</tbody>
</table>

† Assumption of 30 minutes

**RNs and CDEs have few (if any) billable services**
Who Is Covering CGM?

• Vast majority of commercial plans have written coverage for personal and professional CGM
  – Aetna, Cigna, United Healthcare, Humana, HealthNet, Aetna and most of the BC/BS plans
  – Plans may have specific coverage criteria and utilization limits
  – Personal CGM coverage may be limited to Type 1 (with exceptions)

• Medicare Coverage
  – Payment for professional CGM in all 50 states
  – Does not pay for personal CGM devices
# CGM Coverage Criteria: Top Payers

<table>
<thead>
<tr>
<th></th>
<th>Personal CGM</th>
<th>Professional CGM</th>
<th>CPT Codes Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aetna</strong></td>
<td>Age &gt;25 years all Type 1s</td>
<td>Patients with diabetes who have either of the following problems in controlling blood glucose levels or are unresponsive to conventional insulin dose adjustment:</td>
<td>95250 and 95251</td>
</tr>
<tr>
<td></td>
<td>Age &lt;25:</td>
<td>• Type 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Recurrent severe hypos (&lt;50mg/dl) with unawareness that required assistance</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• SMBG 4x/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Will cover twice within a 12 month period</td>
<td></td>
</tr>
</tbody>
</table>

Coverage for T1; no coverage for T2; certificate of medical necessity only.
# CGM Coverage Criteria: Top Payers

<table>
<thead>
<tr>
<th></th>
<th>Personal CGM</th>
<th>Professional CGM</th>
<th>CPT Codes Listed</th>
</tr>
</thead>
</table>
| **United**     | Type 1 diabetes who meet EITHER of the following criteria AND have demonstrated adherence to a physician ordered diabetic treatment plan  
• Unable to achieve optimum glycemic control as defined by the most current version of the ADA Standards of Medical Care OR  
• Have experienced hypoglycemia unawareness. | Not available    | 95250 and 95251  |

Coverage for T1; no coverage for T2; certificate of medical necessity only
# CGM Coverage Criteria: Top Payers

<table>
<thead>
<tr>
<th></th>
<th>Personal CGM</th>
<th>Professional CGM</th>
<th>CPT Codes Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cigna</strong></td>
<td>Age &gt;25 years all Type 1s</td>
<td>Covered for the management of difficult to control insulin-treated diabetes for up to six times in a 12 month period</td>
<td>95250 and 95251</td>
</tr>
<tr>
<td></td>
<td>Age &lt;25:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Type 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Recurrent severe hypos (&lt;50mg/dl)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• SMBG 4x/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Type 2:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Recurrent severe hypoglycemia (&lt;50mg/dl)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• SMBG 4x/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Meet Medicare coverage criteria for insulin pumps such as C-peptide level or renal insufficiency</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Coverage for T1 & T2; certificate of medical necessity, labs for T2, office notes for T1 under 25 years old.
## CGM Coverage Criteria: Top Payers

<table>
<thead>
<tr>
<th></th>
<th><strong>Personal CGM</strong></th>
<th><strong>Professional CGM</strong></th>
<th><strong>CPT Codes Listed</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anthem</strong></td>
<td>- Age &gt; 25 years old with Type 1 diabetes&lt;br&gt;- Inadequate glycemic control, demonstrated by HbA1c measurements between 7.0% and 10.0% despite documented compliance&lt;br&gt;- Insulin injections are required 3 or more times per day or on insulin pump&lt;br&gt;- Four or more fingersticks/day&lt;br&gt;&lt;br&gt;All Type 1 who meet the following criteria:&lt;br&gt;- Recurring episodes of hypoglycemia (less than 50mg/dl); and&lt;br&gt;- Inadequate glycemic control despite four or more fingersticks/day&lt;br&gt;- Insulin injections are required 3 or more times per day or on insulin pump&lt;br&gt;&lt;br&gt;Also covered for Type 1 during pregnancy if above criteria is met</td>
<td>- Type 1 who meet the following criteria:&lt;br&gt;- Fasting hyperglycemia (greater than 150 mg/dl) or recurring episodes of hypoglycemia (less than 50mg/dl); and&lt;br&gt;- Inadequate glycemic control despite four or more fingersticks/day&lt;br&gt;- Insulin injections are required 3 or more times per day or on insulin pump&lt;br&gt;- Monitoring and interpretation under the supervision of a physician; and&lt;br&gt;- Device is only used for 72 consecutive hours on an appropriate periodic basis&lt;br&gt;&lt;br&gt;Approved for use twice a year</td>
<td>95250 and 95251</td>
</tr>
</tbody>
</table>

Coverage for T1 & T2; certificate of medical necessity only.
Next Phase of CGM Reimbursement

• Expanding coverage for Type II patients
• Medicare coverage for personal CGM
• Patient co-pays and deductibles can lead to out-of-pocket costs
  – Not a coverage issue, but how the plan is structured
• Some plans covering personal CGM under pharmacy benefits
• **Coverage** for CGM has continued to improve and is widely available for patients with T1DM and expanding to insulin requiring T2DM.

• **Payment** by individual insurance plans are changing where the out of pocket costs are higher due to higher deductibles. Patients are choosing these higher deductible plans in an effort to reduce their premiums. This is an *insurance plan* issue, not a CGM coverage issue.

• **Coding** is well established for HCPs using CGM in their practice for both the professional and personal training of CGM in the office or diabetes center (95250) as well as the interpretation of CGM data reports (95251).
What Does Healthcare Reform Mean to Diabetes?

• People with diabetes will no longer be denied insurance or forced to pay higher premiums
• Focus on prevention and wellness tools
• Increase focus on Chronic Diseases
• Uninsured people with diabetes will be able to access insurance through high risk pools specifically created to make insurance available until the provisions banning discrimination are fully in place in 2014
Healthcare Reform Already in Place Impacting Diabetes

- No pre-existing conditions exclusion for children
  - Prohibited from excluding children with diabetes from parents insurance
- No cancelling policies; prohibited from rescinding policies
- No lifetime limits on benefits
- Young adults can stay on parents plan up to age 26
- Some preventive services will be free of co-pays and deductible
- Beneficiaries receiving a 50% discount on brand name drugs
Accountable Care Organizations (ACOs)

- Network of providers (primary care doctors, physician specialists, hospitals, and/or home care agencies) that share responsibility for care of patient
- Unlike the current healthcare system, in which providers make money only when treating sick people, ACOs would reward providers with a share of the cost savings achieved by retaining or improving patient health
- Conversely providers may see financial losses if they don't meet benchmarks in patient outcomes and care coordination
Accountable Care Organizations (ACOs)

• Diabetes Educators and other non-physician personnel will be key to the success of these new ACOs which emphasize care coordination, wellness, teamwork and health education — all areas of diabetes educators expertise.

• Although ACO guidelines do not specifically spell out diabetes educator roles, diabetes educators will have a unique opportunity to help patients navigate barriers to care and to educate patients.
Diabetes Supplies Competitive Bidding

• Beneficiaries with fee for service Medicare will have two options to purchase their diabetic testing supplies:
  – Beneficiaries can have their diabetic testing supplies delivered directly to their home by a national mail-order contract supplier (mail-order), or
  – Beneficiaries can pick up their supplies in person from any Medicare-enrolled supplier of diabetic testing supplies (non-mail-order)

• Medicare-approved amount for diabetic testing supplies will be the same regardless of where the supplies are furnished