Living Life with Continuous Glucose Monitors (CGMs)

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Nebraska Medicine

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Life with a CGM

"No, that's not the fire alarm... it's my CGM beeping!"

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Conflict of Interest:

- I have no actual or potential conflict of interest in relation to this presentation.
- The technology field for CGMs is rapidly changing. As a result, adoption of these technologies is gradually rising and healthcare providers needing to be aware.

3

Resources:

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Resources:

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Objectives

- Describe the features of the CGMs available in the US
- Identify patients that would be ideal candidates for CGMs
- Understanding CGM reports
- Describe billing opportunities available for healthcare providers

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- **CGM Background**
- Guideline Recommendations
- CGM Device Features
- Patient Selection & Education
- Data Interpretation Overview
- Coverage and Billing Opportunities

7

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What is a CGM?

- *Continuous glucose monitor*
- Compact medical system that checks blood sugar readings consistently
- Readings every 1 – 5 minutes (15 min)
  – 4 readings a day → 288+ readings a day
- Considered first step in artificial pancreas (1)

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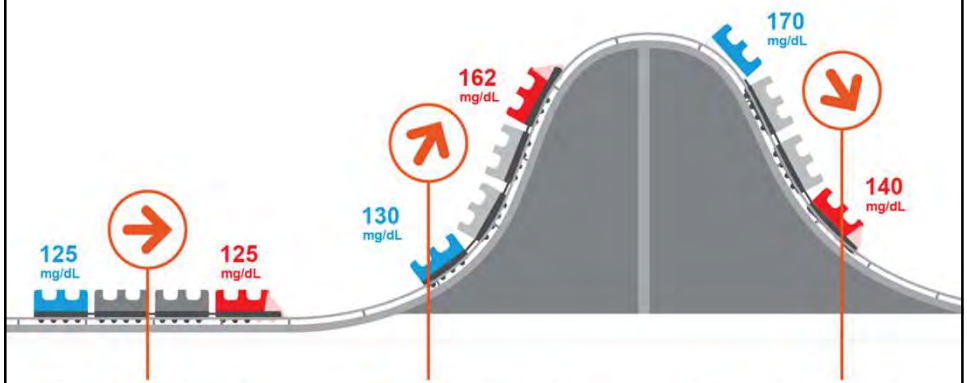
SMBG vs CGM

	SMBG	CGM
Glucose measurement	Capillary reading	Interstitial reading
Lag time	No	Yes
Requires finger stick	Yes	Yes* Some require finger sticks for calibration, during blinded periods, confirmation of hypoglycemia
Overall assessment glucose management	Point in time	Directional arrows- trends Alarms

9 SMBG: self-monitoring of blood glucose Reference 2

9

The FreeStyle Libre Sensor measures ISF glucose instead of blood glucose.
Here is an example to illustrate the lag between blood glucose and sensor glucose:



When glucose level is **stable,** the sensor readings and blood glucose readings are similar.

When glucose level is **trending up,** the sensor readings may be lower than blood glucose readings.

When glucose level **is trending down,** the sensor readings may be higher than blood glucose readings.

10 Reference 33

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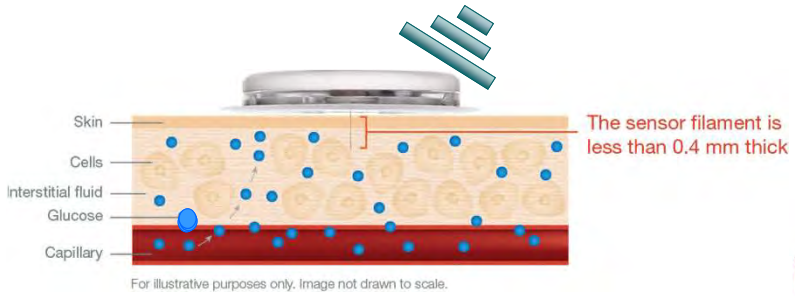
CGM Mechanism/Terminology

- **Sensor**: Filament inserted into the interstitial fluid
  - Back of arm, stomach, lower back (age-related)
- **Sensor** communicates with **transmitter**
  - Sends Bluetooth signal to **receiver**
- **Receiver**: digital readout of blood sugars
  - Phone or physical receiver



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Reference 3, 4, 5

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CGM Types

Personal CGMs

- "Un-blinded"
- Used for insulin dosing and/or therapy adjustments

Professional CGMs

- "Blinded"
- Used to identify trends, detect problems related to diabetes control, change in medication or for patients that might not be good candidates for personal
- May help patients qualify for personal CGM

Flash

- Values stored in sensor
- FreeStyle 14-day® and Libre 2®

Real-time

- Automatically transmit data
- Dexcom, Senseonics, Medtronic, FreeStyle Libre 3®

iCGM

- Integrated continuous glucose monitoring system
- Upgraded designation for use in automated insulin dosing systems

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Reference 6

12

Professional CGMs

- "Blinded CGMs"
- Used to identify glucose trends
- Option for patients whose insurance does not cover personal CGMs or additional supportive data needed for insurance coverage (7)
- Products:
  - FreeStyle Libre Pro®
  - Dexcom G6 Pro®
  - Medtronic-Ipro2

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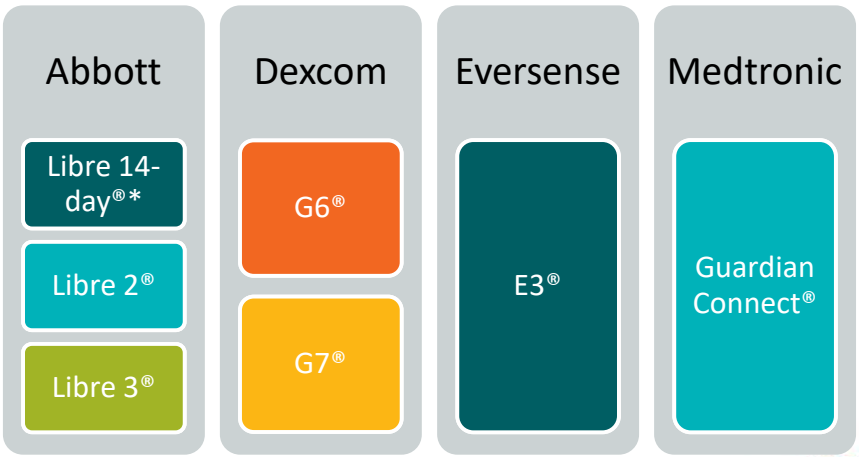
Available CGM Devices in the US



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- CGM Background
- **Guideline Recommendations**
- CGM Device Features
- Patient Selection & Education
- Data Interpretation Overview
- Coverage and Billing Opportunities

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ADA Guidelines, 2023

Patients MUST have SMBG ability and ability to use device

SHOULD be offered CGM

- Multiple daily insulin injections or continuous insulin infusion
- Basal or bolus insulin alone

Choice of device is patient-specific

17 SMBG = self-monitoring of blood glucose Reference 8

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American Association of Clinical Endocrinologists and American College of Endocrinology – 2021

CGM Recommended

- Intensive insulin regimen (3+ injections or pump)
- Problematic hypoglycemia (frequent/severe, nocturnal, hypoglycemia unawareness)
- Children and adolescents
- Patients who are pregnant and on intensive insulin regimens
- Gestational DM on insulin

May be Recommended

- Gestational DM not on insulin
- Patients with type 2 diabetes on less intensive regimens

DM: diabetes mellitus

18 Reference 9

18

Evidence for use in T1DM

Change in A1c	↓ 0.4% - 1.0%
Decreased time in hypoglycemia	↓ 2% - 46%
Increase in patient satisfaction	Yes

19 Reference 10

Reference 9

19

Evidence for use in T2DM

Significant change in A1c	Multiple daily injections; basal only; oral	rtCGM & isCGM
Decreased time in hypoglycemia	Multiple daily injections	isCGM

20 Reference 10

20

- CGM Background
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Accuracy of CGMs

- Mean Absolute Relative Difference (MARD)
  - Average of absolute error
- MARD <10% considered safe for insulin dosing
  - No goal mandated for FDA approval
  - Some concern about mathematical limitations
  - MARD % do vary depending on study but all within the range.

	MARD *(%)*
DexcomG6®	9.8%
DexcomG7®	8.2%
Eversense E3®	8.5%
FreeStyle Libre®	9.4%
FreeStyle Libre2®	9.3%
FreeStyle Libre3®	9.2%
Medtronic®	8.9 – 9.6%

22 Reference 36

Device Features

- Trend arrows
- Alarms
- Pump interoperability
- Calibration
  - Unless noted otherwise, CGMs should not be calibrated unless system requests calibration OR SMBG reading highly differs from CGM

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Trend Arrows

- Visual representations of aggregate trend data
- Calculations and angle unique to each system
- Point in time vs long-term

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Trend Arrows for all CGMs

Dexcom G5/G6*		Guardian Connect		FreeStyle Libre		Eversense	
Arrow	Meaning	Arrow	Meaning	Arrow	Meaning	Arrow	Meaning
⇈	Glucose rapidly rising >3 mg/dL/min >0.2 mmol/L/min	⇈	Glucose rapidly rising >3 mg/dL/min >0.2 mmol/L/min	—	—	—	—
↑	Glucose rising 2–3 mg/dL/min 0.1-0.2 mmol/L/min	↑	Glucose is rising 2–3 mg/dL/min 0.1-0.2 mmol/L/min	↑	Glucose rapidly rising >2 mg/dL/min >0.1 mmol/L/min	↑	Glucose rapidly rising >2 mg/dL/min >0.1 mmol/L/min
↗	Glucose slowly rising 1–2 mg/dL/min 0.06-0.1 mmol/L/min	↑	Glucose slowly rising 1–2 mg/dL/min 0.06-0.1 mmol/L/min	↗	Glucose rising 1–2 mg/dL/min 0.06-0.1 mmol/L/min	↗	Glucose slowly rising 1–2 mg/dL/min 0.06-0.1 mmol/L/min
→	Glucose steady *Increasing/decreasing* <1 mg/dL/min <0.06 mmol/L/min	–	Glucose steady Increasing/decreasing <1 mg/dL/min <0.06 mmol/L/min	→	Glucose steady *Increasing/decreasing* <1 mg/dL/min <0.06 mmol/L/min	→	Glucose steady *Increasing/decreasing* <1 mg/dL/min <0.06 mmol/L/min
↘	Glucose slowly falling 1–2 mg/dL/min 0.06-0.1 mmol/L/min	↓	Glucose slowly falling 1–2 mg/dL/min 0.06-0.1 mmol/L/min	↘	Glucose slowly falling 1–2 mg/dL/min 0.06-0.1 mmol/L/min	↘	Glucose slowly falling 1–2 mg/dL/min 0.06-0.1 mmol/L/min
↓	Glucose falling 2–3 mg/dL/min 0.1-0.2 mmol/L/min	⇊	Glucose is falling 2–3 mg/dL/min 0.1-0.2 mmol/L/min	↓	Glucose rapidly falling >2 mg/dL/min >0.1 mmol/L/min	↓	Glucose rapidly falling >2 mg/dL/min >0.1 mmol/L/min
⇊	Glucose rapidly falling >3 mg/dL/min >0.2 mmol/L/min	⇊	Glucose rapidly falling >3 mg/dL/min >0.2 mmol/L/min	—	—	—	—

*Arrows appear differently in G5/G6 touchscreen receiver and smartphone displays.

25 Reference 31

Alarm Basics

- Current
  - Blood glucose
  - Rate of change
- Predictive (fall/rise)
- Personalize alarm settings
  - Higher in geriatrics, “brittle” patients, hypoglycemia unawareness

26 Reference 32

Pump Integration

- Includes algorithms to automatically adjust insulin rates or completely suspend insulin in response to CGM readings

Medtronic®	• MiniMed 630G • Medtronic 770G and 780g with SmartGuard
Dexcom G6®*	• Tandem t:slim X2 with Basal-IQ • Tandem t:slim X2 with Control-IQ • OmniPod 5
Dexcom G7, Libre 2 and 3	• CGMS that will be integrated with automated insulin delivery systems soon. • Tandem Tslim 2 with CIQ, Tandem Mobi, Omnipod 5, Ilet beta bionic

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Dexcom G6®

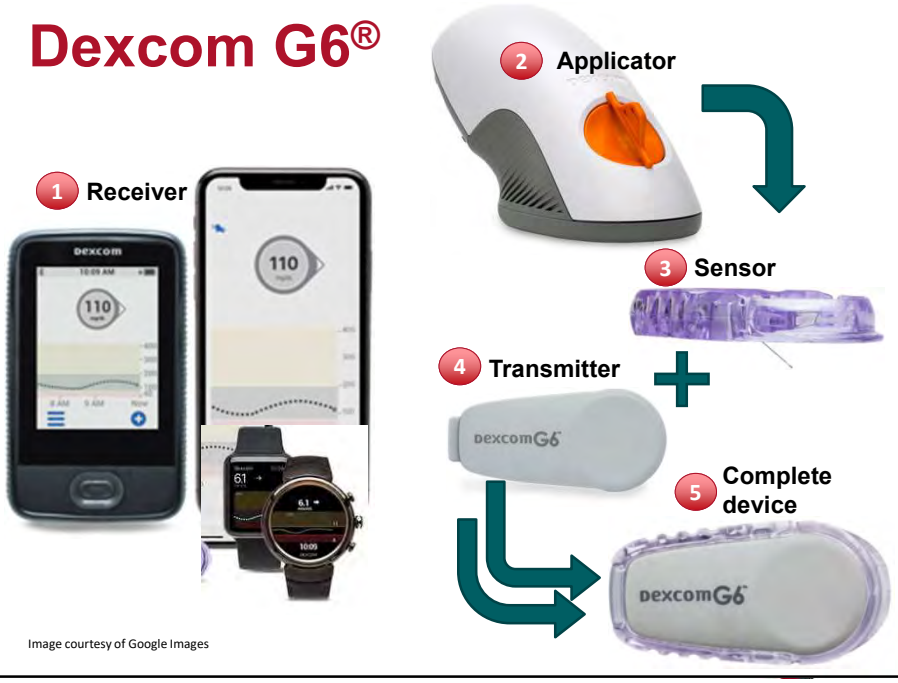

Image courtesy of Google Images

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Dexcom G6®

Approved ages	• 2+ years old
Pump Integration	• Tandem T-Slim, Omnipod 5 Ilet Beta Bionic
Calibration	• No
Dose insulin	• Yes
Insertion site	• Abdomen (back of arm, upper buttock)
Duration	• 10 days
Alarms	• High, low, predictive
Apps	• Android, Apple
Interacting Substances	• Acetaminophen: doses >1g every 6H • Hydroxyurea

29 Reference 11

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Dexcom G7®

30 Image courtesy of Google Images

30

Dexcom G7®

Approved ages	• 2+ years old
Pump Integration	• Coming soon
Calibration	• No
Dose insulin	• Yes
Insertion site	• Back of arms (7+), upper buttocks (2-6 years old)
Duration	• 10 + .5 days
Alarms	• High, low, predictive, delayed notifications
App	• Android, Apple
Interacting Substances	• Unclear; suspect same as G6

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Eversense E3®

32 Reference 14

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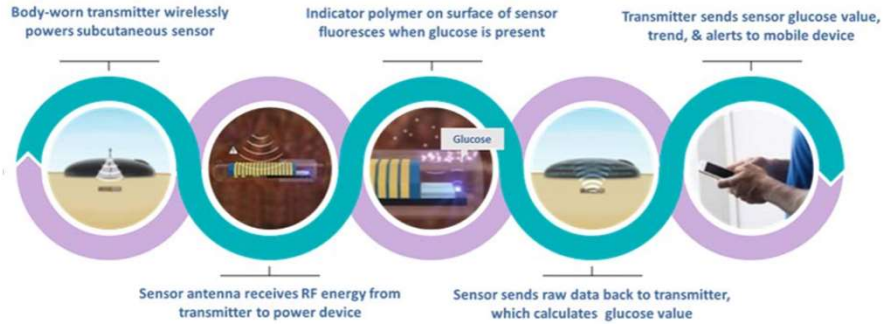
Eversense® Mechanism



33 Reference 15

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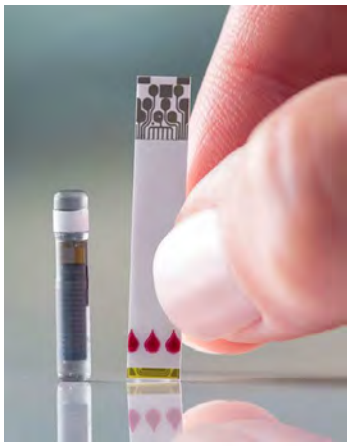
Warm-Up Period – Eversense®

- Contains a drug-eluting silicone ring
- Releases dexamethasone acetate
  - Minimize the inflammatory effect



Reference 16

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Eversense E3®

Approved ages	• 18+ years
Pump Integration	• No-hopefully soon
Calibration	• 3 phases
Dose insulin	• Yes
Insertion site	• Upper arm
Duration	• 180 days
Alarms	• High, low, predictive*
App*	• Android, Apple
Interacting Substances	• IV Mannitol or sorbitol • Tetracyclines • Long-term dexamethasone

- **Initial**: 4 calibrations in 2-24 hours
- 2 calibrations per day for at least first 21 days
- Then 1-2 calibrations per day

35 Reference 17

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FreeStyle Libre 2®

36 Reference 12

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FreeStyle Libre 2®

Approved ages	• 4+ years
Pump Integration	• No-coming soon-different version
Calibration	• No
Dose insulin	• Yes
Insertion site	• Back of upper arm
Duration	• 14 days
Alarms	• Real-time
App	• Apple, Android
Interacting substances	• Ascorbic Acid (>500mg/day)

37 Reference 13

37

FreeStyle Libre 3®

2 **Receiver**

1 **Sensor/ Transmitter**

38 Reference 13

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FreeStyle Libre 3®

Approved ages	• 4+ years
Pump Integration	• No-coming soon
Calibration	• No
Dose insulin	• Yes
Insertion site	• Back of upper arm
Duration	• 14 days
Alarms	• Real-time
App	• Apple, Android
Interacting substances	• Ascorbic Acid (>500mg/day)

39 Reference 13

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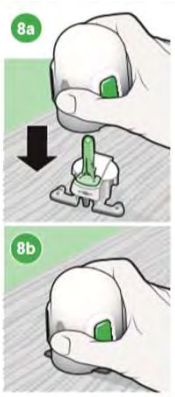
Medtronic Guardian Connect Sensor 3®



3 Applicator

4 Sugar IQ App

2 Receiver

1 Sensor/ Transmitter

Guardian Sensor 3 measures glucose levels under your skin.

Guardian Connect transmitter* connects to your glucose sensor and sends glucose readings to your app.

Guardian Connect app shows glucose readings on your own cellular phone or mobile device.

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Medtronic Guardian Connect Sensor 3®

Approved ages	• 14 – 75 years old
Pump Integration	• Yes*
Calibration	• Every 12 hours*
Dose insulin	• No*
Insertion site	• Back of upper arm, stomach
Duration	• 7 days
Alarms	• Real-time
App	• Apple and Android*
Interacting Substances	• Acetaminophen (any dose) • Alcohol

41 Reference 19

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Medtronic Guardian Connect Sensor 4®

Approved ages	• 14 – 75 years old
Pump Integration	• Yes*-780g
Calibration	• One time to get into Smart Guard then as needed
Dose insulin	• Yes
Insertion site	• Back of upper arm, stomach
Duration	• 7 days
Alarms	• Real-time
App	• Apple and Android*
Interacting Substances	• Acetaminophen (any dose) • Alcohol

42 Reference 19

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43 Reference 18

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- Data Interpretation Overview
- Coverage and Billing Opportunities

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Patient Selection

Supportive data for disease state

Patient psychology and behaviors

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American Association of Diabetes Educators

Should be considered if:	May pose challenges for:
• Adequate insurance coverage/able to afford copays • Hypoglycemia unawareness, frequent/severe hypoglycemia, nocturnal hypoglycemia. • Suspected eating disorders • Pre, peri, post-pregnancy • Interested in improving diabetes management	• CGM costs unaffordable • Extreme anxiety/paranoia about hypo and hyperglycemia • Significant body image issues • Disengaged with self-care • Unmanageable skin allergies/reactions to adhesives

47 Reference 28

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Psychological Impact of CGMs

Reference 29

48

Selecting the Ideal Patient

Lower diabetes distress	Higher diabetes distress
Lower self-efficacy	Higher self-efficacy
Negative attitudes towards technology	Positive attitudes towards technology

Reference 30

49

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CGMs REQUIRE EDUCATION

**Although Dexcom and Libre are marketed as self-start*

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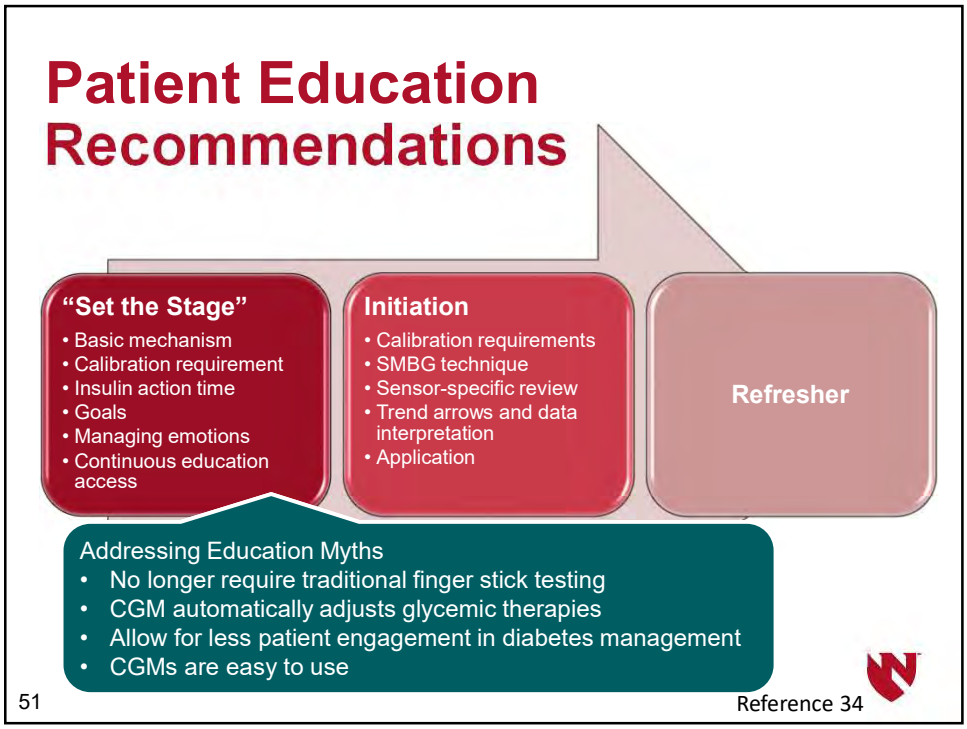
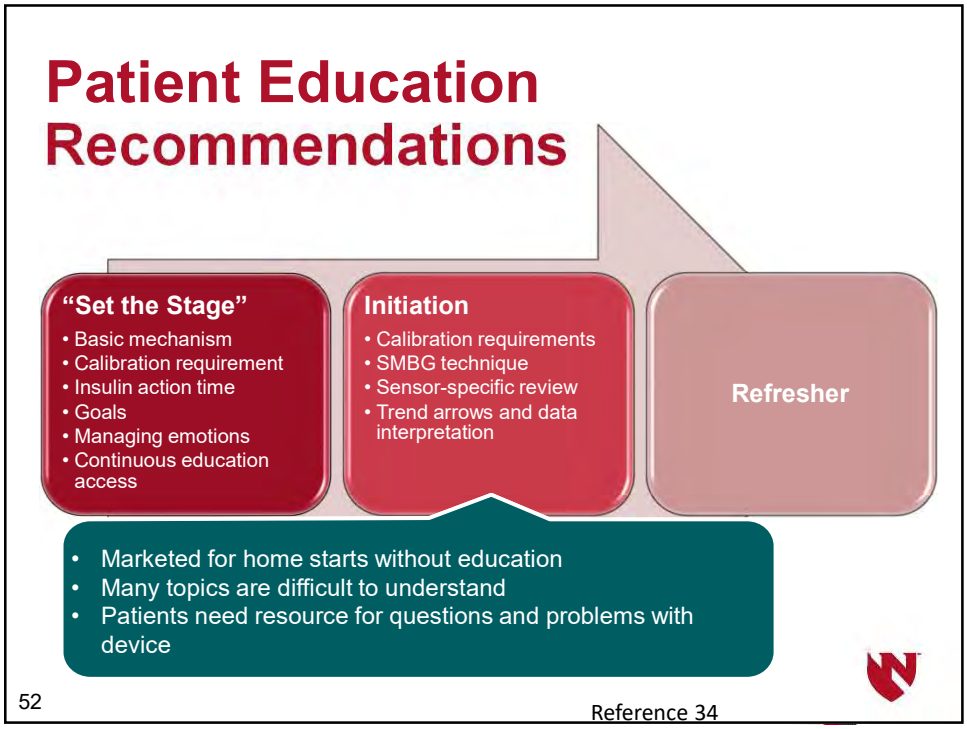

Patient Education Recommendations
"Set the Stage"
• Basic mechanism
• Calibration requirement
• Insulin action time
• Goals
• Managing emotions
• Continuous education access
Initiation
• Calibration requirements
• SMBG technique
• Sensor-specific review
• Trend arrows and data interpretation
• Application
Refresher
Addressing Education Myths
• No longer require traditional finger stick testing
• CGM automatically adjusts glycemic therapies
• Allow for less patient engagement in diabetes management
• CGMs are easy to use
51
Reference 34

51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• Calibration requirements
• SMBG technique
• Sensor-specific review
• Trend arrows and data interpretation
Refresher
• Marketed for home starts without education
• Many topics are difficult to understand
• Patients need resource for questions and problems with device
52
Reference 34

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Patient Education Recommendations

"Set the Stage"
- Basic mechanism
- Calibration requirement
- Insulin action time
- Goals
- Managing emotions
- Continuous education access

Initiation
- Calibration requirements
- SMBG technique
- Sensor-specific review
- Trend arrows and data interpretation

Refresher
- Review data, including how it is interpreted
- Identify potential problem areas with use

53 Reference 34

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CGM Issues

- That one patient that doesn't understand why his cgm won't stay on!!

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Attachment Assistance

Skin Barrier

- Chemical or physical barrier between a patient and their device
- As device wear time increases, skin reactions increase
- Skin Tac™

Skin Adhesive

- Chemical or physical aid used to enhance adhesion
- Adhesion time threatened by extended wear time, sweat, patients bumping/pulling on device
- Skin Tac™, Matisol, adhesive patches, Tegaderm

*Manufacturer education handouts

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Attachment Assistance

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CGM/Skin Irritation

- **Items to use BEFORE putting on next site/sensor:**
- Milk of magnesia works well to help Heal up the skin as well as works like a barrier. It's the least expensive so you would take a q-tip and spread a thin layer on the skin., let it dry and then put the cgm/tape on top of this. You can also use the milk of magnesia with a thin layer on the skin after you remove the cgm for skin irritation.
- Some people are also able to just use Flonase nasal spray/Clearispray to the area for protection. Apply 1 puff of flonase to the area of skin and let it dry then apply the cgm.
- Consider putting tape down first with cgm on top of that-under patch, hydrocolloid bandaid, Hy-tape

Removal:

- When removing site - but sure to use baby oil or calendula-soaked cotton ball to soften the adhesive. Uni-solve or glue remover to help with irritation.
- If having issues after site removal, you can use Benadryl ointment/cream to minimize swelling and irritation.

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CGM/Skin Irritation

- **Here's a more detailed thing that you could try but involves a lot more steps:**
- 1. Wash area with warm water and antibacterial soap-no use alcohol-based soap
- 2.Completely dry the area
- 3. Apply one puff of flonase
- 4. Apply thin layer of cavilon barrier cream/Milk of magnesia and let this dry
- 5. Apply tegaderm HP 6x7
- 6. Place dexcom on top/thru the tegaderm and can apply an overlay patch or tegaderm on top.
- 7. When wet-blow dry with dryer
- 8. When removed apply hydrocortisone cream
- 9.Remove adhesive with calendula oil or baby oil

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- CGM Background
- Guideline Recommendations
- CGM Device Features
- Patient Selection & Education
- **Data Interpretation Overview**
- Coverage and Billing Opportunities

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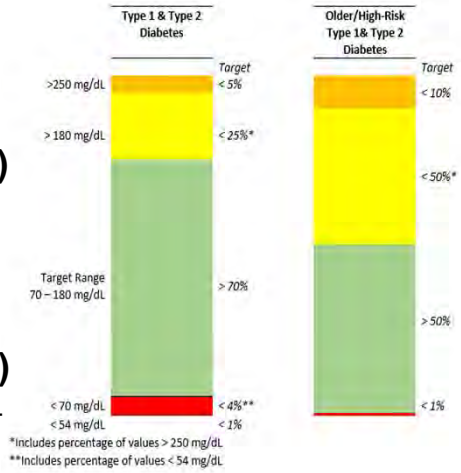
Terminology

- **Time in range (TIR)**
  - Relates to prevalence, severity of diabetes complications, A1C
- **Time above range (TAR)**
  - Level 1 hyperglycemia: 181 – 250 mg/dL
  - Level 2 hyperglycemia: > 250 mg/dL
- **Time below range (TBR)**
  - Level 1 hypoglycemia: 54 – 69 mg/dL
  - Level 2 hypoglycemia: < 54 mg/dL



61 Reference 21

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Terminology

Data Sufficiency

Glucose Management Index (GMI)

- Estimated A1c

Glucose Variability (GV)

- Coefficient of variation (CV)
  - <36%
- Standard deviation (SD)

62 Reference 22

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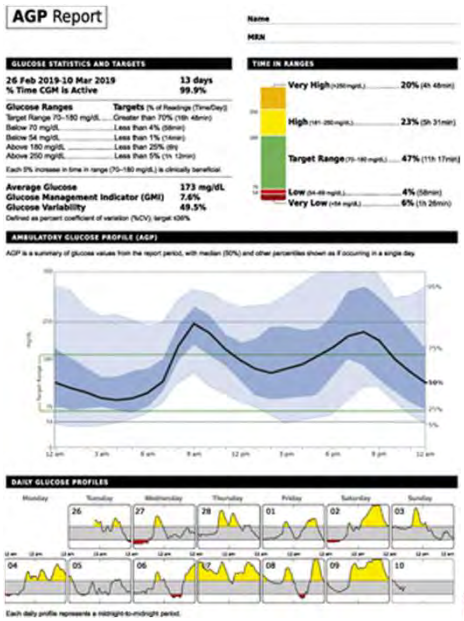
Ambulatory Glucose Report

Consider geriatric patient BG. Recent A1c and GMI at 7.6%; goal 7.5%

Current regimen:
Metformin XR 500mg – 2 tabs PO BID
Lantus 10 units subq daily



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Reference 35

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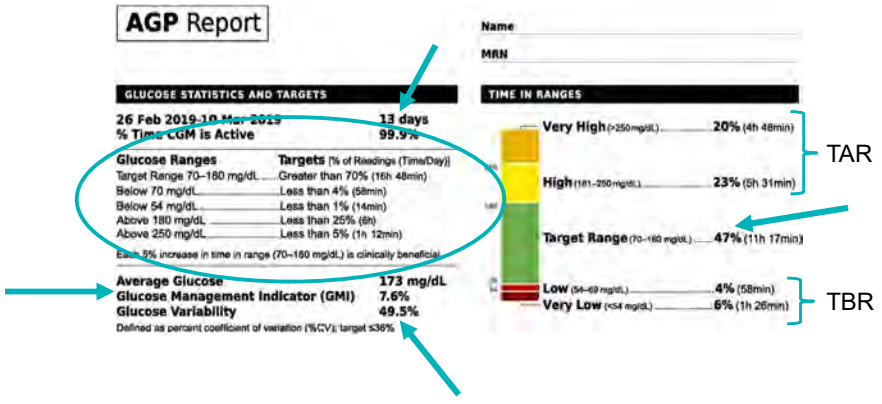
AGP Report – Part 1



64 AGP = ambulatory glucose profile report

Reference 35

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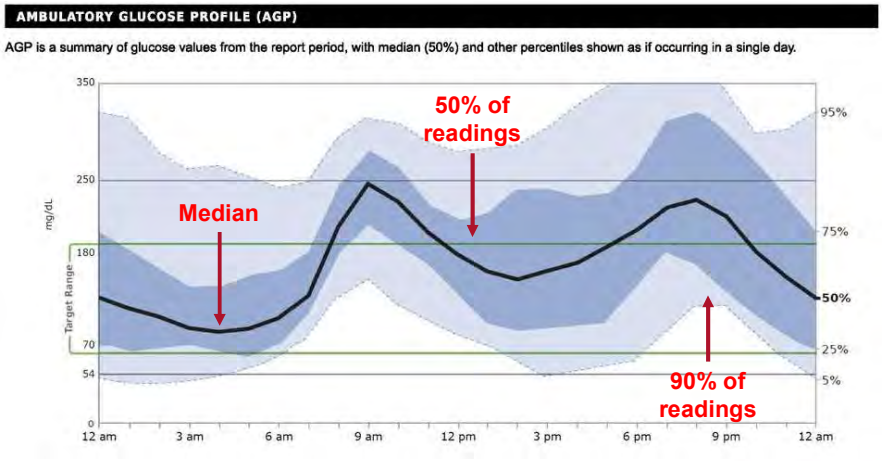
AGP Report – Part 2



65 Reference 35

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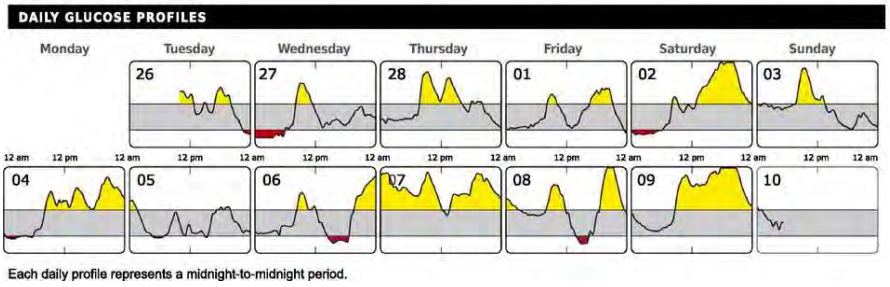
AGP Report – Part 3



66 Reference 35

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- CGM Background
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- **Coverage and Billing Opportunities**

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Monthly Maintenance Cost

Dexcom G6® Dexcom G7	• Sensor: $140 • Transmitter: $297 every 3 months • Dexcom G7-$150-$180 range • Good RX coupon, Costo, patient/pharmacy assistance programs
Eversense®	• Sensor, transmitter, adhesives, insertion: $300-$600, some estimations don't include insertion fee. • Patient access program - $99 for sensor that is for 6 months bringing it to $16.50 per month- • Average cost for insertion-$240-for first insertion, $400 for removal/2nd sensor insertion with annual cost of $600 so $50.00/month
FreeStyle Libre2& Libre 3®	• Sensor: $30-$75 • E-savings voucher to reduce cost and discount at certain pharmacies
Medtronic Connect/Guardian®	• Sensor and transmitter:$397-$500 • Patient assistance/pharmacy assistance programs. Discount cost for monthly supplies.
CGM coverage	Danatech has cgm coverage tool: https://danatech.policyacumen.health/?state[]=NE

Coverage and reimbursement. FreeStyleLibre. [2019].
Tenderich, A. *Healthline: Diabetes Mine.* March 18, 2019.
Hoskins M. *Healthline: Diabetes Mine.* February 19, 2020.
Continuous glucose monitoring: The costs. *Medtronic-diabetes.com.*

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Medicare A&B-Personal

- DM diagnosis or who have hypoglycemia-meets 1 of the criteria.
  1. 2 or more BS <54 that persist despite multiple modifications to treatment plan.
  2. One level 3 hypoglycemic event (glucose <54 mg/dL) characterized by altered mental and/or physical state requiring third-party assistance for treatment.
- 1 insulin injection per day or insulin pump
  Advantage plans-3 insulin injections per day or insulin pump. Some DME companies will cover for 1 injection per day
- Frequent regimen adjustments
- In-person visit with treating practitioner within 6 months

69 Reference 25

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Medicare Products

Dexcom G6® and G7

FreeStyle Libre2® and Libre 3

Eversense

Medtronic Guardian

All products must go through DME distributor. Noted some plans may have pharmacy coverage.

70 Reference 24

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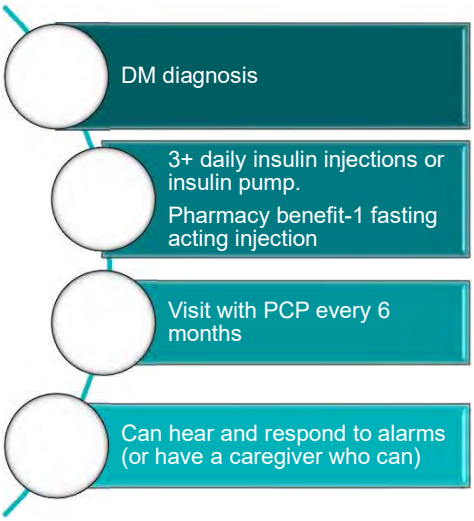
Medicaid- Personal



PLUS one of the following:

- A1c elevated above goal
- Hypoglycemia unawareness
- Recurring episodes of hypoglycemia
- Unexplained episodes of nocturnal hypoglycemia

71 Reference 26

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Commercial – Personal

DM diagnosis, Gestational Diabetes, Hypoglycemia

DM diagnosis

Testing 4+ times per day, not always required especially if pharmacy benefits

3+ daily insulin injections or insulin pump

Frequent regimen change

Regular visits with provider

Additional glycemic concerns

REQUIREMENTS RANGE

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Professional CGMs

Commercial & Medicare: covers quarterly for diagnostic purposes for patients with DM or hypoglycemia. Some plans allow for every 1-2 months for professional placement.

Nebraska Medicaid: covers quarterly if…

3+ doses of insulin daily	Seen by provider every 6 months	A1c above goal OR hypoglycemia unawareness OR nocturnal hypoglycemia

73 Reference 23

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CGM Billing Opportunities

Billing Code	95249	95250	95251
Title	Education and placement of **personal** or patient-owned CGM	Education and placement of **professional** or **clinic**-owned CGM	Analysis and Interpretation of data
Covers:	Sensor placement, hook-up, calibration of monitor, patient training, printout of recording	Sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, printout of recording	Covers 72+ hours of data analysis **requires billing under provider*
Reimbursement Potential (NE)	Medicare: $49.84 - $54.45 Commercial: $128 *1.73 RVUs*	Medicare: $121.35 - $151.57 Commercial: $309 *4.38 RVUs*	Medicare: $35.30 Commercial: $97 *1.02 RVUs*
Frequency	Once per device lifetime	4x/year	Medicare: Once per 1-2 months Medicaid: 8x/year No more than monthly

74 Reference 20

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Cost-effectiveness of CGMs

CGM reduces DKA events & hospitalizations by 80%

2014: ~$5 billion

2022: ~$6.2 billion

2023: ~$4.96 billion

DKA = diabetic ketoacidosis

Reference 27

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Conclusions

CGMs are useful devices for select patients

- T1DM: clear benefit for A1c and hypoglycemia reduction
- T2DM: benefit for A1c and hypoglycemia reduction less clear
- Cost barrier
- Extensive education

Select CGM based on patient characteristics

- Features of selected CGM reflect the needs of the patient
- Settings of selected CGM personalized to patient

CGMs offer billing opportunities for pharmacists

- Recurrent billing options
- Service development opportunity

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Questions?

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