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Ohio Cardiovascular and Diabetes Health Collaborative



*In partnership with:*



Cardi-OH ECHO

# *What's New in Cardiovascular Prevention? A Series of Case-Based Discussions*

September 22, 2022

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# Person-Centered Language Recommendations



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The ADA and the APA recommend language that emphasizes inclusivity and respect:

- **Gender**: Gender is a social construct and social identity; use term “gender” when referring to people as a social group. Sex refers to biological sex assignment; use term “assigned sex” when referring to the biological distinction.
- **Race**: Race is a social construct that is used broadly to categorize people based on physical characteristics, behaviors, and geographic location. Race is not a proxy for biology or genetics. Examining health access, quality, and outcome data by allows the healthcare system to assist in addressing the factors contributing to inequity.
- **Sexual Orientation**: Use the term “sexual orientation” rather than “sexual preference” or “sexual identity.” People choose partners regardless of their sexual orientation; however, sexual orientation is not a choice.
- **Disability**: The nature of a disability should be indicated when it is relevant. Disability language should maintain the integrity of the individual. Language should convey the expressed preference of the person with the disability.
- **Socioeconomic Status**: When reporting SES, provide detailed information about a person’s income, education, and occupation/employment. Avoid using pejorative and generalizing terms, such as “the homeless” or “poor.”
- **Violent Language**: Avoid sayings like ‘killing it,’ ‘pull the trigger,’ ‘take a stab at it,’ ‘off the reservation,’ etc.



# Continuous Glucose Monitoring

Karen Bailey, MS, RDN, LD, CDCES

*Ohio University*

# Learning Objectives



1. List indications for CGM
2. Identify candidates and strategies for successful CGM use
3. Describe recent device innovations in CGM
4. Describe insurance coverage requirements for CGM devices in Ohio

# Definition of CGM (continuous glucose monitors)



- A device that constantly measures glucose levels in interstitial body fluid (every 1 to 5 minutes, 24 hours/d). Parts include a sensor, a transmitter, and a receiver.
- rtCGM – real time CGM streams data continuously to the receiver
- isCGM – intermittently scanned CGM requires the transmitter to be scanned by the receiver to obtain a reading by the user.
- Provide alerts for designated low and high glucose levels



Dexcom G6



Abbot FreeStyle Libre 2



Senseonics Eversense



Medtronic Guardian 8

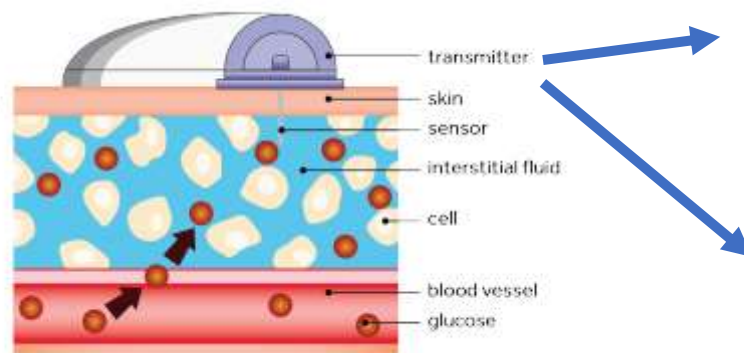
# How CGMs Work

## Sensor Glucose (SG) and Blood Glucose (BG)

Your glucose meter and glucose sensor measure glucose levels in two different places.

Your **BG meter** measures glucose in your blood.

The **glucose sensor** measures glucose in the fluid around the cells called **interstitial fluid**.



- Sensor is inserted most often on the abdomen or arm, depending on device.
- Transmitter is attached to a sensor or the transmitter and sensor are one piece, depending on device.
- Transmitter sends the glucose level and trend data (arrows indicating direction of glucose and speed) to a receiver (smart device, receiver, or linked insulin pump, depending on device).
- The sensor glucose will not be identical to bg, especially if bg is moving quickly, such as after meal, insulin, or exercise. The algorithm gives close estimate but is helpful for the user to understand this. <sup>9</sup>



# Professional vs Personal CGMs



Professional CGM	Personal CGM
Owned by clinic	Owned by person with diabetes
Blinded or unblinded options- for evaluation of diabetes control by provider	Unblinded (real time or scan for sg)- allows user to receive sensor data, receive high and low alerts designated by user
Short term use (3 to 14 days)	Long term use: the various sensors last different number of days each (7 days, up to 180 days, depending on sensor)
Insurance coverage for most with Type 1 or Type 2 diabetes	Insurance coverage for people on intensive insulin regimens or diabetes not in control.
Not compatible with insulin pumps or connected insulin pens	Compatible with insulin pumps, smartphones or connected insulin pens, depending on device

Wright LA, Hirsch IB. *Diabetes Technol Ther.* 2017;19(suppl 2):S16-S26; Kruger DF, et al. *Diab Educ.* 2019;45(suppl 1):S3-S20.

# Professional CGM



	Dexcom G6 Pro	LibrePro
Blinded vs unblinded	Both	Blinded
Maximum wear time of sensor	10 days	14 days
Calibration	None	None
Downloading reports	Clarity	LibreView
Care between transmitter use	Disposable-1 time use, must attached transmitter	Disposable 1-time use, combined sensors/transmitter
Alarms for high/low glucose alerts	Yes	No
Interfering substances	Hydroxyurea	Salicylic acid and high-dose vitamin C

## Personal CGM Comparison (FDA approved products)

	G6	Libre 2	Libre 3	Guardian Connect or Guardian 3	Eversense
<b>Integration</b>	T: Slim X2, Omnipod 5, InPen	Bigfoot Unity	No	Medtronic 770G, InPen	No
<b>Display device</b>	Smartphone or receiver	Smart phone or reader	Smartphone only	Smartphone or insulin pump	Smartphone only
<b>Maximum wear time</b>	10 days	14 days	14 days	7 days	180 days
<b>Warm-up time</b>	2 hours	1 hour	1 hour	Up to 2 hours	24 hours
<b>Calibrations required</b>	0	0	0	At least 2/day	2/day for 21 days, then 1/day
<b>FDA approved sites</b>	Abdomen (ages 2+) Upper buttocks (ages 2-17)	Upper arm	Upper arm	Upper arm, abdomen Upper buttocks (ages 7-13)	Upper arm
<b>FDA Approved for dosing (non-adjunctive indication)</b>	Yes	Yes	Yes	No	Yes
<b>FDA Approved ages (years)</b>	≥2	≥4	≥4	≥2 Guardian 3 ≥14 Guardian Connect	≥18
<b>Drug Interactions</b>	Hydroxyurea	Vitamin C	Vitamin C	Acetaminophen, Hydroxyurea	Tetracycline antibiotics, mannitol
<b>MARD</b>	9%	9.2%	7.9%	9.64%	8.5%
<b>Alarms</b>	High, Low, Predictive	High, Low	High, Low,	High, Low, Predictive	High, Low, Predictive

ADCES Practice Paper. The Diabetes Care and Education Specialist Role in CGM. Available at: <https://www.diabeteseducator.org/practice/educator-tools/diabetes-management-tools/self->

\*MARD = mean absolute relative difference. Lower MARD values indicate greater device accuracy.



## Components of the Dexcom CGM

The Dexcom CGM System consists of three parts:

1. a small sensor that measures glucose levels just underneath the skin
2. a transmitter that fits onto the sensor and sends data wirelessly to your display device
3. a small receiver or compatible smart device<sup>†</sup> that displays real-time glucose information<sup>‡</sup>

The Dexcom CGM also provides customizable alerts to warn the wearer of approaching glucose highs and lows.

Dexcom G6 requires no calibration, can be used to make treatment decisions and is covered by Medicare Part B (must include reader) for qualified members, and Ohio Medicaid (pharmacy benefit for qualified members) and many private insurers.

# Dexcom G7

- Status:
  - Approved CE mark in Europe
  - Pending FDA approval in USA
- Improvements:
  - Improved accuracy
  - Decreased size (half the size of Dexcom G6)
  - Approved locations: Abdomen, Back of the arm
  - Reduced Warm up period (2 hours down to 30 minutes)
  - 12-hour grace period to replace expired sensors
- Compatibility:
  - Meets iCGM criteria



<https://www.dexcom.com/g7-ce-mark>

# Abbot FreeStyle Libre 2 intermittently scanned CGM (isCGM)



Abbott FreeStyle Libre 2 does not require calibration. Sensor and transmitter are one disposable piece. Sensor/transmitter is worn for 14 days. The FreeStyle Libre 2 allows user to enter alerts for highs and lows. The older, FreeStyle Libre 14-day wear does not have alert option. FreeStyle Libre 2 is covered by Medicare for qualified beneficiaries. Reader needs to scan sensor for user to see a reading. The FreeStyle Libre 3 will not require scanning and will be smaller but will not include a reader. Users must have a smart phone with compatible app.

# Medtronic Guardian Connect and Guardian 3 CGM



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Guardian Connect  
CGM/app



Guardian 3  
CGM/MiniMed Mobile app



- Requires calibration and decisions on treatment should be made based on fingerstick bg measure. Rechargeable transmitter. Sensors last 7 days.
- Medicare covers Guardian 3 CGM only if integrated with Medtronic insulin pump.
- Guardian Connect CGM links with InPen and smart phone app.



Senseonics  
Eversense E3  
CGM now  
approved for  
180-day wear.

Must have smart  
phone that has  
compatible app.

Requires  
fingerstick  
calibration.

**FDA Approved!**

**Eversense CGM  
Fully Implantable  
for 90 Days**



**1 Make incision**  
5-8 mm incision upper arm (lidocaine)



**2 Create subcutaneous pocket**  
Approximately 3-5 mm below skin surface



**3 Insert sensor**  
Sensor placed with custom inserter



**4 Close incision**  
Steri-Stripe™ to close





## Personal CGM Products

Current	Next Generation
Freestyle Libre 2	Guardian 4
Freestyle Libre 3	Dexcom G7
Dexcom G6	
Eversense 90 & 180 day	
Guardian Connect & Guardian 3	

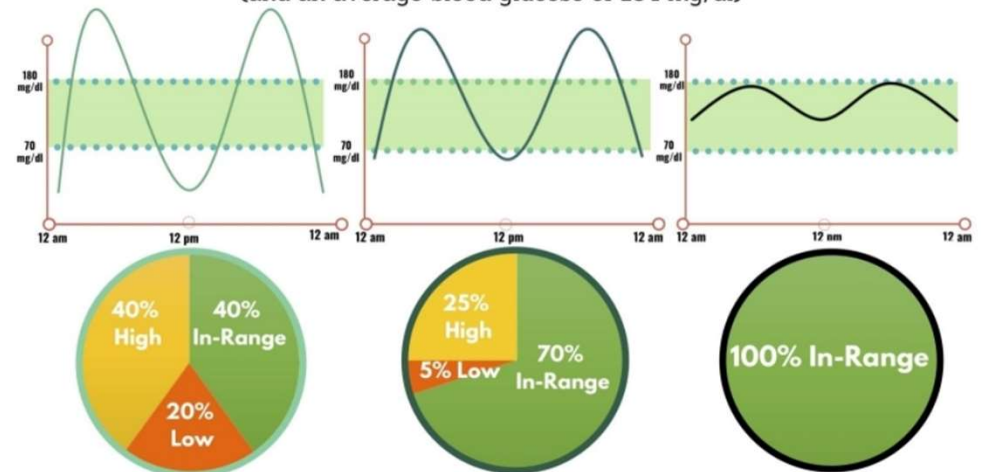
# Benefits of CGM Use

- CGM gives a more complete picture of glucose fluctuations throughout the day, compared to HbA1c
- Real-time data allows user to see the effect of various foods, exercise, medications, and stress on glucose levels, even as they sleep
- Gives users alerts if sensor glucose levels are approaching highs or lows set by user.
- Improves quality of life measures in people with diabetes on insulin.

## A1C Alone is Just Not Enough

### THE MANY FACES OF A 7% A1C

(and an average blood glucose of 154 mg/dl)



<https://diatribe.org/time-range>.

# Who Should Be Prescribed a CGM?



**Any of the following may be an indication for Personal CGM: Type 1 or Type 2 Diabetes.**

- Taking multiple daily injections of insulin
- Using an insulin pump
- Frequent hypoglycemia
- Hypoglycemia unawareness
- High degree of glycemic variability
- Not achieving glucose targets



# 2022 Standards of Medical Care in Diabetes



## **Summary recommendations- individuals with diabetes should be offered CGM if:**

- adults on multiple daily injections or CSII (insulin pumps)
- adults on basal insulin not in target
- youths with type 1 or type 2 diabetes on multiple doses of insulin or CSII
- pregnant females with diabetes as an adjunct to pre and postprandial blood glucose monitoring

Individuals seeking CGM or their caregivers should be able to use the devices safely and the choice of device should be made based on patient circumstances, desires, and needs.

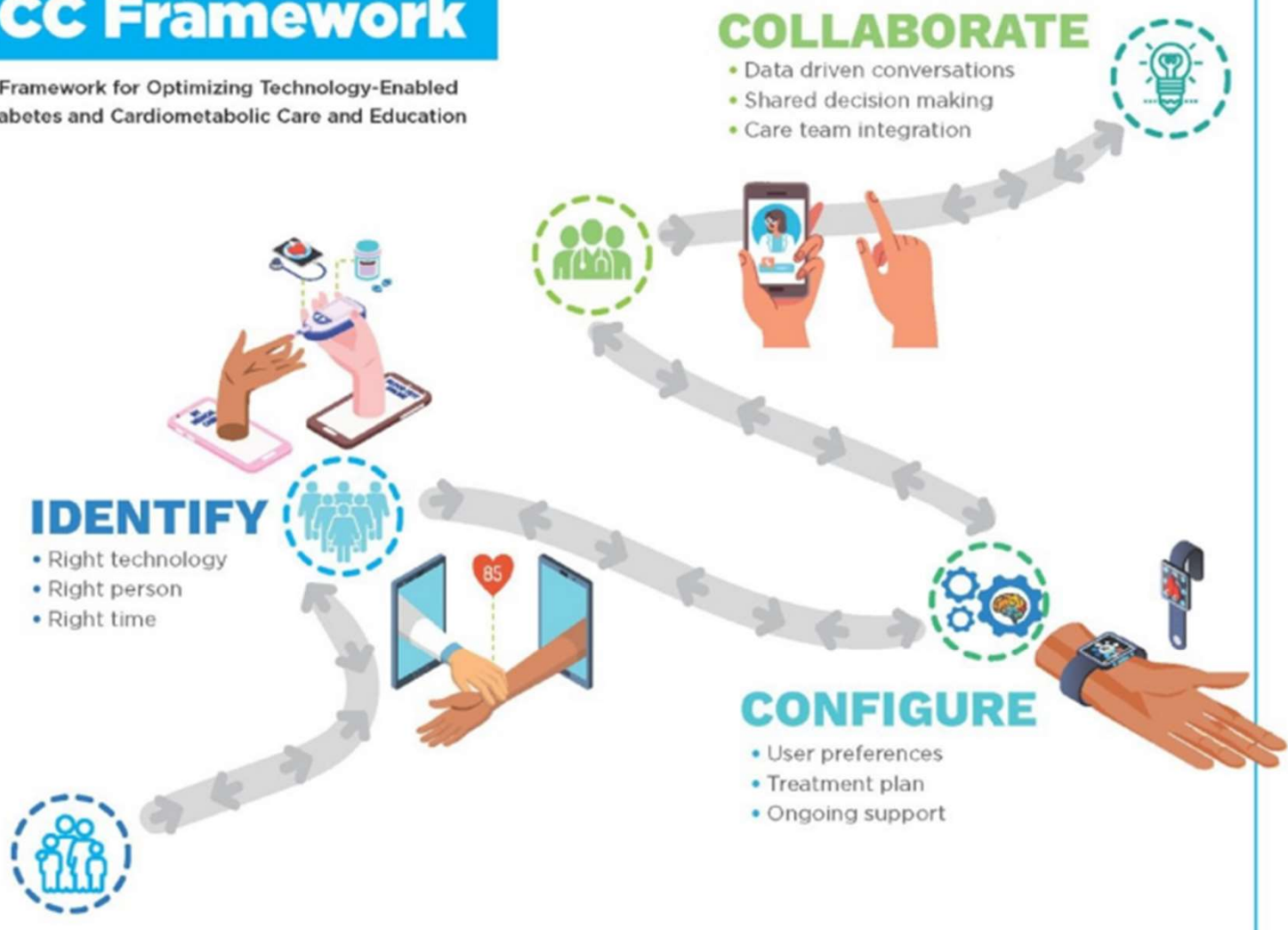
## **Configure: The Importance of Education & Training**



“No device used in diabetes management works optimally without education, training, and follow-up.”

# ICC Framework

A Framework for Optimizing Technology-Enabled Diabetes and Cardiometabolic Care and Education



Isaacs, D. et al. Technology-Integration: The Role of the Diabetes Care and Education Specialist. TDE. 2020; 46(4): 323-334.



Collaborate with individuals using a shared decision-making approach following the DATAA model.<sup>8</sup> Review Dexcom CGM reports using CLARITY software to facilitate data driven discussions.

**D**



**DOWNLOAD DATA**

- Ensure open communication to facilitate meaningful discussion
- Ask the person with diabetes what's going well for them
- Download or view data in CLARITY clinic
- Review glucose metrics and patterns within CLARITY reports (Overview, Daily, AGP, Compare etc.)

**A**



**ASSESS SAFETY**

- Ask the person with diabetes if they've experienced hypoglycemia
- If hypoglycemia is present, engage in interactive discussion around potential reasons and realistic solutions
- Review % time below range and glucose variability
- Re-configure Dexcom G6 alarms and alerts as needed
- Discuss the value of sharing CGM data with family or friends through the Dexcom G6 app

**T**



**TIME IN RANGE**

- Start with the "Best Day" pattern in the CLARITY Overview report to discuss what's working well and how to do more of those activities
- Review progress towards time-in-range goals
- Use CLARITY weekly push notifications or email summaries to track progress towards newly defined goals

**A**



**AREAS TO IMPROVE**

- Reinforce that all data provide information and CGM values are not "good" or "bad"
- Review time above range and identify possible causes, solutions and adjustments to self-management
- Tailor education based on data to provide person-centered care
- Review use of Trend Arrows in Dexcom G6 app and how to treat for hypoglycemia or adjust insulin for hyperglycemia<sup>9</sup>

**A**



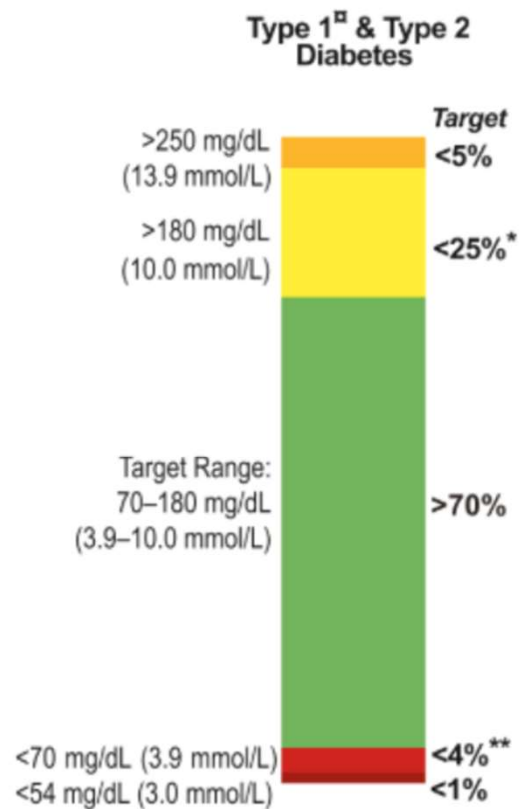
**ACTION PLAN**

- Collaboratively engage in feedback
- Encourage engaging in personal experiments choosing one small change at a time (healthy eating, being active etc.)
- Discuss potential changes in the treatment plan
- Identify ongoing support needs
- Plan for follow up



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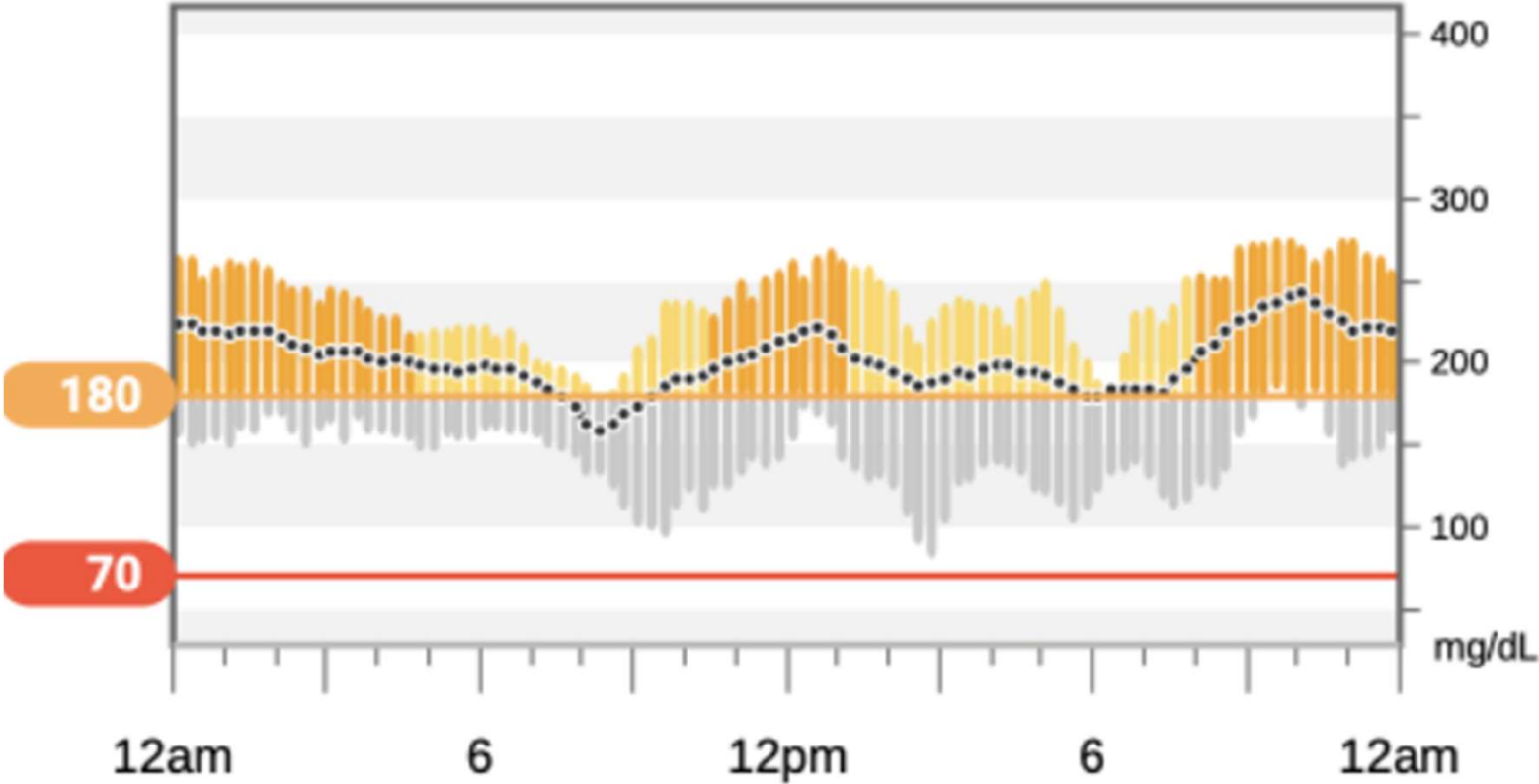
# Interpreting CGM Downloads: Recommendations for Time in Range



Consensus on Time in Range. Diabetes Care 2019 Jun; dci190028.



# Interpreting CGM Downloads:



# CMS coverage criteria for CGM include that the patient must:



1. Have a diagnosis of diabetes, either type 1 or type 2
2. Require frequent dosing of insulin (3/day)
3. Require frequent adjustment of diabetes treatment regimen

Order must include a durable CGM receiver. Covered under Medicare Part B as durable medical supply



# Ohio Medicaid coverage criteria for CGM include that patient:

*Adoption of New Ohio Administrative Code Rule 5160-10-36*



Has type 1 or type 2 diabetes and one of more of the following conditions:

- Frequent insulin dosing or on insulin pump
- Has HbA1c outside the target range
- Fasting or postprandial hyperglycemia
- Unexplained hypoglycemic episodes despite appropriate changes in insulin therapy
- Hypoglycemia unawareness
- Have microvascular complications
- Have a condition (ex, epilepsy) that makes hypoglycemia management difficult
- Recurrent DKA

No PA required, pharmacy benefit

# Questions to ask when helping PWD decide on device appropriateness



- Do you have a diagnosis of type 1 or type 2 diabetes?
- Are you on an insulin pump that may integrate with one of the sensors on the market? If not, do you plan to use an insulin pump in the near future? Which one?
- If not on insulin pump, are you on frequent dosing of insulin (3 or more)? (If Medicare beneficiary)
- Do you have a smart phone? If so, can you download one of the apps? (Dexcom G6, FreeStyle Libre 2 or 3, Medtronic Connect, or Eversense)? Do you have internet connectivity at home? If not, select sensor with a reader.
- Can you see the reader or app screen and read words on the screen?
- Can you hear well enough to hear low or high alerts?
- Do you know what your bg targets are?
- What insurance coverage do you have?

# Educate for optimal CGM outcomes



- Help set up reader or app on cell phone. Help apply CGM to body, start warm up. Instruct on CGM removal. Instruct on help line for device malfunctions.
- The difference between sensor glucose and blood glucose (larger difference when bg is moving up or down rapidly, such as after meals, after insulin, during and after exercise).
- Sensor glucose accuracy improves with wear compared to first day of wear.
- Calibrations may be required for some CGMs
- Certain substances may interfere with sensor accuracy (hydroxyurea for Dexcom, > 500 mg/d Vit C for FreeStyle Libre, for example)
- Avoid alarm fatigue! Discuss realistic high and low alerts for PWD you are with. Teach how to set and change alert settings.
- Teach PWD how to troubleshoot highs and lows:
  - Educate on what makes bg go up (food, stress, certain medications, monthly cycle, illness, forgetting medication for diabetes or taking too small a dose)
  - Educate on what makes bg go down (too long between meals, more than usual activity, too much medicine, alcohol intake)
- Help PWD connect CGM to professional account and help PWD download share app for family members if desired.



Thank you!

Questions/Discussion