

Financial Disclosure and Resolution

Under guidelines established under the Standards for Integrity and Independence in Accredited Continuing Education, disclosure must be made regarding relevant financial relationships with ineligible companies within the last 24 months.

I have no relevant financial relationships with ineligible companies to disclose.

Professional Practice Gap

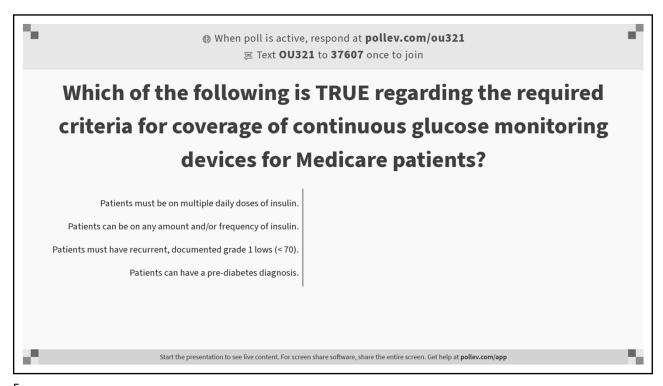
- Medicare, Medicaid, and some commercial plans recently updated the criteria for continuous glucose monitoring (CGM) device coverage
 - Greatly increased CGM accessibility for type 2 diabetes (T2DM) patients
 - Still inertia with acquiring and utilizing CGMs
- Pharmacists, in collaboration with other providers, can be involved with:
 - Ordering CGMs
 - Educating patients on CGMs
 - Interpreting key metrics of CGMs

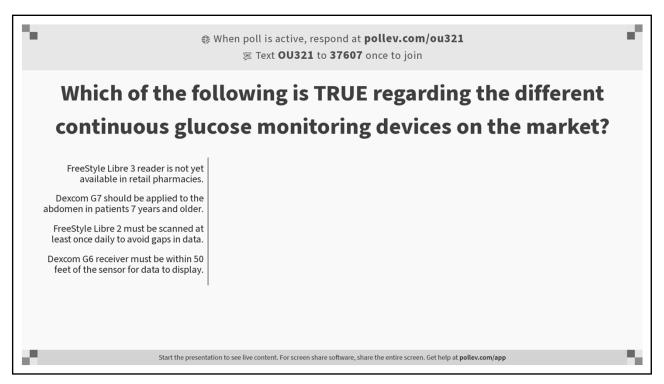
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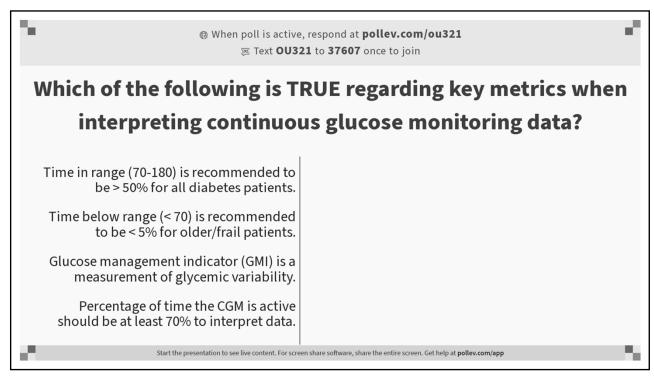
Learning Objectives

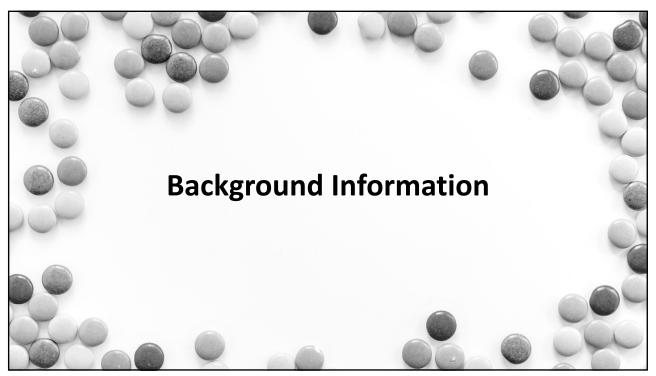
At the completion of this activity, *pharmacists* will be able to:

- 1. Describe the recent expansion of continuous glucose monitoring (CGM) coverage
- 2. Recognize the benefits of CGM use compared to traditional glucose monitoring
- 3. State the differences of personal CGM devices on the market
- 4. Recall recommendations pertaining to the procurement, usage, and interpretation of CGMs

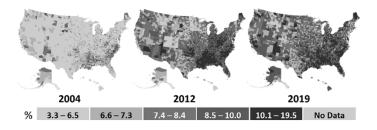








Diabetes Prevalence



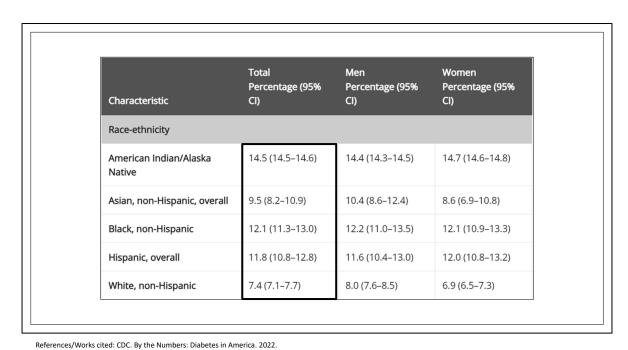
- Among the U.S., 37 million (11%) have diabetes
 - 28.7 million diagnosed, 8.5 million undiagnosed
 - Type 2 diabetes = 90-95% of cases
- Among Oklahoma, 400,000 (13%) have diabetes

References/Works cited: CDC. National Diabetes Statistics Report. 2022.

References/Works cited: CDC. By the Numbers: Diabetes in America. 2022.

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Characteristic	Population Estimates, 2019 ^a Number in thousands (95% CI)	Incidence Estimates, 2018–2019 Rate per 1,000 (95% CI)
Total	1,398 (1,234–1,562)	5.9 (5.0-6.9) ^b
Age in years		
18-44	401 (309-493)	3.2 (2.3-4.4) ^b
45-64	703 (583–823)	10.1 (8.1–12.5) ^b
≥65	293 (230–356)	5.8 (4.3-7.8) ^b



Characteristic	Total Percentage (95% CI)	Men Percentage (95% CI)	Women Percentage (95% CI)
Education			
Less than high school	13.4 (12.5–14.4)	12.2 (10.9–13.6)	14.8 (13.5–16.2)
High school	9.2 (8.7-9.6)	10.2 (9.5–11.0)	8.3 (7.8-8.9)
More than high school	7.1 (6.8–7.5)	7.6 (7.1–8.1)	6.7 (6.3–7.2)
Family income to poverty	ratio		
Less than 100% FPL	14.1 (13.1–15.2)	13.7 (12.0–15.5)	14.4 (13.2–15.7)
100-299% FPL	10.8 (10.3–11.4)	11.1 (10.4–11.9)	10.6 (9.9–11.4)
300-499% FPL	7.8 (7.3–8.3)	9.1 (8.4–9.9)	6.6 (6.0-7.2)
500% FPL or more	5.6 (5.2-6.1)	6.4 (5.8–7.1)	4.8 (4.3-5.3)

Review: Glycemic Monitoring

Hemoglobin A1c

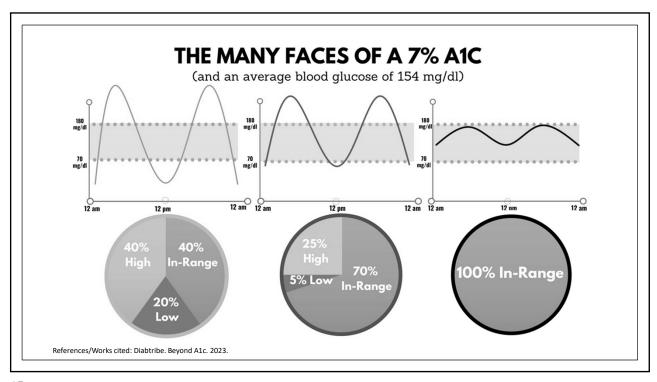
- Average blood glucose over last 3 months
- · Used by clinicians and in clinical trails
- Check every 3-6 months (depending on control)
- · Blood glucose monitoring
 - Snapshot of blood glucose
 - Used by patients and clinicians
 - · Frequency of checks depends on drug therapy
- Continuous glucose monitoring (CGM) increasingly important role!

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HbA1c Limitations

- Indirect measurement, affected by conditions and medications...
 - Most anemias (deficiencies in iron, folate, or B12), asplenia, uremia (typically due to kidney failure), chronic alcohol use, chronic opioid use→ FALSELY ELEVATED A1c
 - Hemolytic anemia, anemia of chronic disease, blood transfusions, splenomegaly, liver cirrhosis, pregnancy, certain HIV medications \rightarrow FALSELY LOW A1c
 - Less common Hb variants and vitamin C use → VARIABLE EFFECTS on A1c
- Race/ethnicity may also impact A1c more research needed
- No indication of variability in blood glucose throughout the day

References/Works cited: Radin MS. J Gen Intern Med. 2014 Feb; 29(2): 388–394.



Review: Glycemic Monitoring

- Hemoglobin A1c
 - Average blood glucose over last 3 months
 - Used by clinicians and in clinical trails
 - Check every 3-6 months (depending on control)

Blood glucose monitoring

- Snapshot of blood glucose
- Used by patients and clinicians
- Frequency of checks depends on drug therapy
- Continuous glucose monitoring (CGM) increasingly important role!

FSBG Limitations

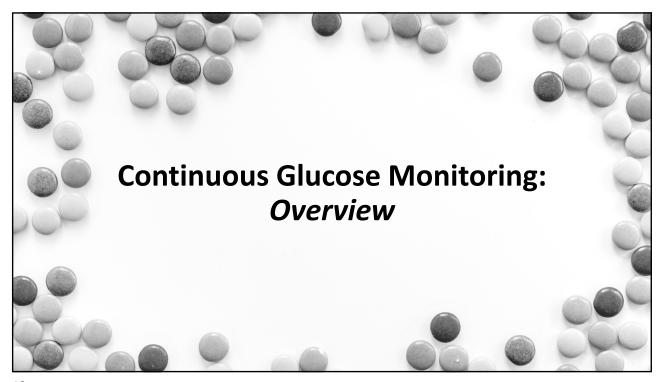
- Several supplies needed
 - Requiring patient education and added costs
 - Burden for patient to carry supplies
- Relies on patient to remember to check
 - Non-insulin/basal insulin only prefer at least 3-4x/week to once daily (fasting BG)
 - Basal + bolus insulin therapy prefer closer to 4x/day (pre-meal BGs, bedtime BG)
- Accuracy
 - Needs to be timed with meals either before a meal or 2 hours after a meal
 - · Test strips should be stored correctly and not expired
- · Difficulty with use
 - · Good dexterity required
 - Complaints of pain

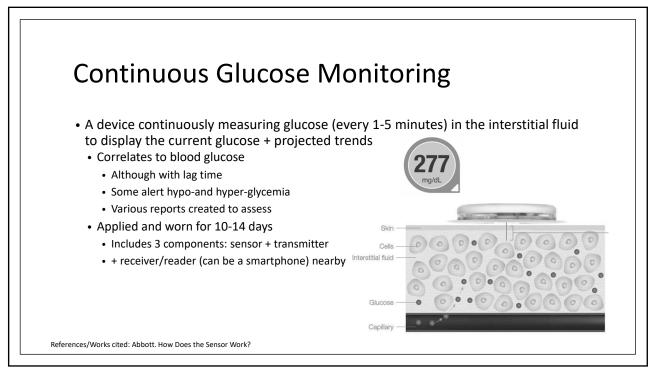
FSBG: Finger-Stick Blood Glucose

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Review: Glycemic Monitoring

- Hemoglobin A1c
 - Average blood glucose over last 3 months
 - · Used by clinicians and in clinical trails
 - Check every 3-6 months (depending on control)
- · Blood glucose monitoring
 - Snapshot of blood glucose
 - Used by patients and clinicians
 - · Frequency of checks depends on drug therapy
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Types of CGMs

<u>Professional:</u> owned by the clinic for short-term use, insurance coverage for most all diabetes patients <u>Personal:</u> owned by the patient for long-term use, insurance coverage standards have recently changed



<u>Intermittently scanned CGM (isCGM):</u> only displays values when scanned (must scan at least every 8 hours)

FreeStyle Libre 14-day

FreeStyle Libre 2 - can be integrated with other digital devices



Real-time CGM (rtCGM): displays values continuously

Dexcom G6, Dexcom G7 - can be integrated with other digital devices

FreeStyle Libre 3 - can be integrated with other digital devices

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Types of CGMs

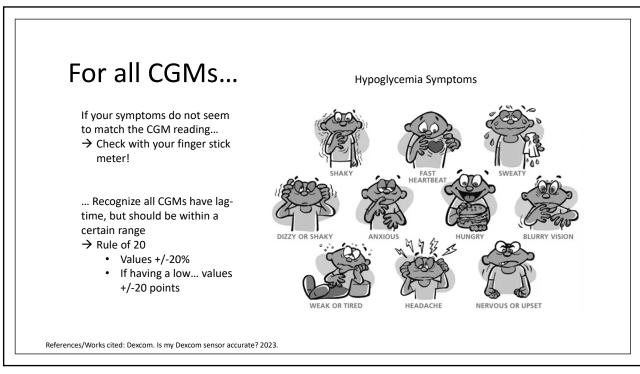
Adjunctive

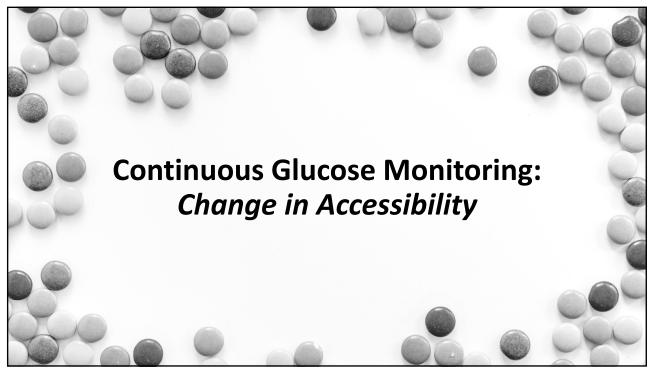
- Requires fingerstick verification for treatment decisions
- Medtronic Guardian (rtCGM)

Non-adjunctive

- Does NOT require fingerstick verification for treatment decisions
 - Dexcom G6 (rtCGM)
 - Dexcom G7 (rtCGM)
 - FreeStyle Libre 14-day (isCGM)
 - FreeStyle Libre 2 (isCGM)
 - FreeStyle Libre 3 (rtCGM)
 - Eversence (implantable CGM)







Evidence Expanding to Type 2 Diabetes

Adults with	Adults with Type 2 Diabetes				
Study	Patients	ссм	A1c Outcomes	Other Outcomes	
Beck et al. 2017	158 pts on MDI	Dexcom	A1c adj. mean difference of -0.3% (p=0.002)	No change in hypoglycemia	
Ehrhardt et al. 2015	100 pts <i>not</i> on prandial insulin (50% oral tx only)	Dexcom	A1c difference of -0.6% (p=0.002)	Not applicable	
Haak et al. 2017	224 pts on MDI or insulin pump	Libre	Only difference in A1c if age < 65 years (p=0.03)	Time < 70 reduced by 43% (p=0.0006)	
Martens et al. 2017	175 pts on basal insulin only	Dexcom	A1c adj. mean difference of -0.4% (p=0.02)	Adj. mean difference: • Time < 70 -0.1% (p=0.001) • Time < 54 -0.24% (p=0.02)	
Yoo et al. 2017	65 pts on oral agents or insulin	Guardian	A1c improved greater by 0.5% (p=0.004)	No significant changes in hypoglycemia	

MDI: Multiple Daily Injections

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General ADA Guideline Points

- Acceptable outcome measurement for clinical trials moving forward
- CGMs are meeting patient needs
 - Data can serve as an A1c surrogate
 - Useful for evaluating/creating more personalized treatment plans
 - While only FDA approved for outpatient use, patients should be allowed to use CGMs inpatient if have all supplies and are well enough

The ADA guidelines have discussed CGMs for years... so why the significant increase in accessibility?

References/Works cited: ADA. Diabetes Care. 2023;46:S111-127.

Accessibility Changes

- COVID-19 pandemic
 - Significant ramifications of poorly managed diabetes as many as 40% of Americans who died of COVID-19 had diabetes
 - Effects of the pandemic even more pronounced in underserved areas those of lower income and of color were twice as likely to die
 - CGM use and coverage expanded due to need for remote monitoring to minimize contact/use of PPE access to health insurance being a strong predictor of CGM use

References/Works cited: ADA. Health Equity and Diabetes Technology.

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ADA 2021 Study Results

Those most affected by diabetes were the least like to use CGMs

Children younger than 18 use CGMs significantly more than those 45-64 of age

Black Americans are at the most pronounced disadvantage for CGM use

Individuals with Medicaid are the least likely with CGM access

References/Works cited: ADA. Health Equity and Diabetes Technology.

Medicare & Oklahoma Medicaid

- Criteria for CGM coverage:
 - Diabetes mellitus diagnosis
 - Insulin-treated

OR

- Problematic hypoglycemia, must be ≤ 20 years for Medicaid
 - Recurrent/documented lows < 54
 - Any history of a low < 54 → altered state requiring third party assistance
- Patient is sufficiently trained and has follow-up at least every 6 months

References/Works cited: CMS, Glucose Monitors, 2023.

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Commercial Plans

- Coverage varies from plan to plan, but several have expanded coverage...
 - Dexcom exclusive coverage, regardless of diagnosis
 - CVS Caremark
 - HealthChoice
 - Aetna
 - Dexcom referred coverage, need a diagnosis and similar to CMS criteria
 - Express Scripts
 - Cigna
 - BlueCross BlueShield
 - OptumRx
 - United Healthcare
 - Elevance Health (Anthem)

Out-of-Pocket Pricing

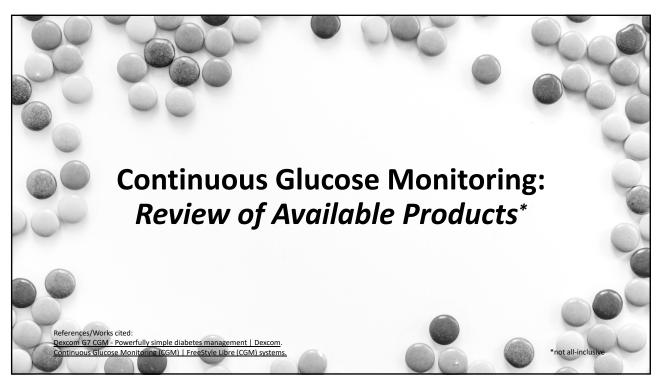
- FreeStyle Libre is most affordable if paying out-of-pocket
- Sensors should never be more than \$75/month

Patients can fill their Rx at a participating pharmacy[‡] with their choice of either a FreeStyle Libre 2 or FreeStyle Libre 3 system — a more affordable CGM^{§1}

If patients are asked to pay >\$75 for two sensors or have questions about coverage and costs, please have patients call 844-330-5535

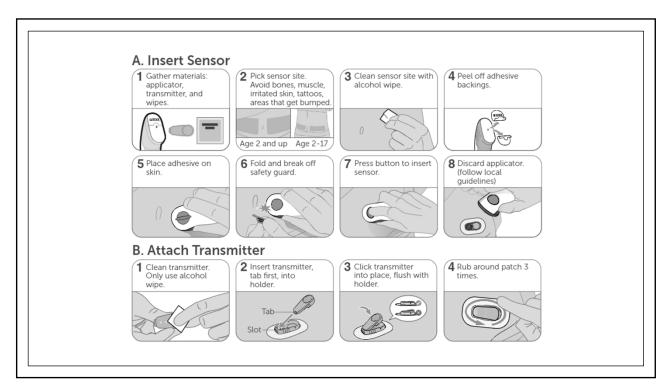
References/Works cited: Abbott. Prescribing Instructions: FreeStyle Libre Systems. 2023.

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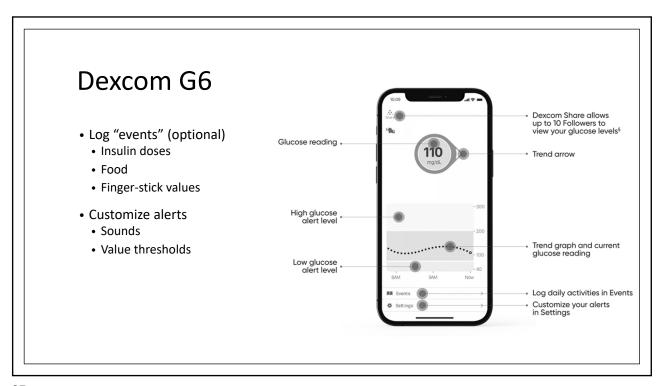
	Dexcom G6	Dexcom G7	FreeStyle Libre 2	FreeStyle Libre 3
Туре	rtCGM		isCGM	rtCGM
FDA approval	<u>></u> 2 yrs	≥ 2 yrs, pregnancy	≥ 4 yrs, pregnancy	
Application site	Abdomen, upper buttocks (2-17 yrs)	Upper arm (7+ yrs), upper buttocks (2-6 yrs)	Upper arm	
Wear-time	10 days	10.5 days	14 days (soon to be 15 days)	
Transmitter	Reusable, 90 days	All-in-on, disposable	All-in-on, disposable	
Warm-up time	2 hours	30 minutes	1 hour	
Alerts	Real-time	Real-time, more customizable	Real-time	Real-time, more customizable
Water depth	8 feet, up	to 24 hours	3 feet, up to	30 minutes
Calibration	Not needed, optional			
Interactions	Hydroxyurea		Vitan	nin C
Integration	Yes, multiple options	Not yet	Yes, multiple options	Not yet
MARD	9.0%	8.2%	9.2%	7.9%





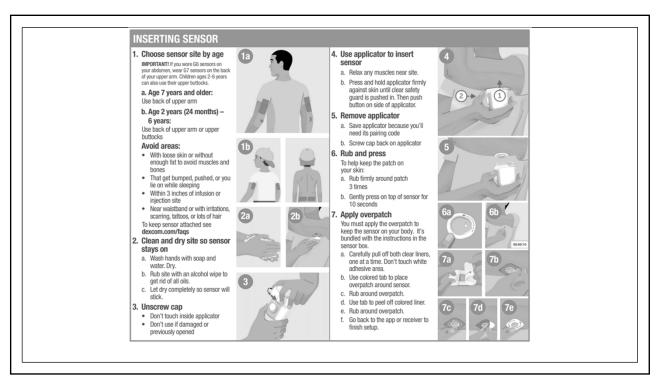
Dexcom G6

- Senses/displays values every 5 minutes
- Pairs with a smart phone via Bluetooth and/or a touchscreen receiver
 - Must be within 20 feet of sensor
 - Compatible smart phones: <u>Dexcom Products & G6 Compatibility with Smartphone Devices | Dexcom</u>
 - Smart phone use requires applications
 - Dexcom G6 must always be running in the background and Bluetooth on
 - Clarity required to share data with healthcare providers
 - Dexcom Follow can share with up to 10 followers
 - Also compatible with Glooko, Tidepool, Livongo, and Apple watch
 - · Receiver use requires USB plug-in to review data fully



	Dexcom G6	Dexcom G7	Freestyle Libre 2	Freestyle Libre 3
Туре	rtCGM		isCGM	rtCGM
FDA approval	≥ 2 yrs	≥ 2 yrs, pregnancy	≥ 4 yrs, pregnancy	
Application site	Abdomen, upper buttocks (2-17 yrs)	Upper arm (7+ yrs), upper buttocks (2-6 yrs)	Upper arm	
Wear-time	10 days	10.5 days	14 days (soon to be 15 days)	
Transmitter	Reusable, 90 days	All-in-on, disposable	All-in-on, disposable	
Warm-up time	2 hours	30 minutes	1 hour	
Alerts	Real-time	Real-time, more customizable	Real-time	Real-time, more customizable
Water depth	8 feet, up to 24 hours		3 feet, up to	30 minutes
Calibration	Not needed, optional			
Interactions	Hydroxyurea		Vitan	nin C
Integration	Yes, multiple options	Not yet	Yes, multiple options	Not yet
MARD	9.0%	8.2%	9.2%	7.9%





Dexcom G7

- Senses/displays values every 5 minutes
- Pairs with a smart phone via Bluetooth and/or a non-touchscreen receiver
 - Must be within 20 feet of sensor
 - Compatible smart phones: <u>Dexcom Products & G6 Compatibility with Smartphone Devices | Dexcom</u>
 - Smart phone use requires applications
 - Simplified **Dexcom G7** app that has **Clarity** integration however, still requires separate Clarity app to share data with healthcare providers
 - Dexcom Follow can share with up to 10 followers
 - Also compatible with Glooko, Tidepool, Livongo, and Apple watch
 - Receiver use requires USB plug-in to review data fully

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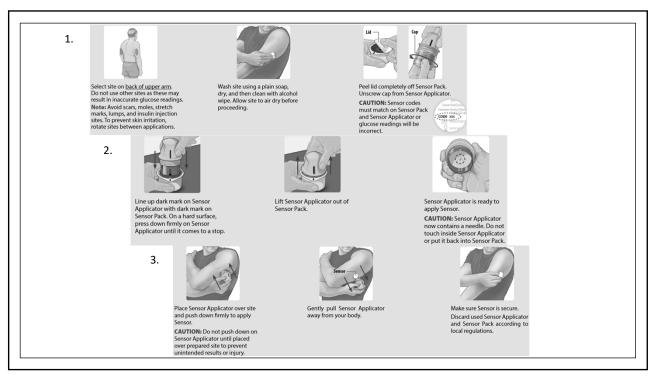
Dexcom G7

- Log "events" (optional)
 - Insulin doses
 - Food
 - Finger-stick values
- Customize alerts + functions for enhanced discretion



	Dexcom G6	Dexcom G7	FreeStyle Libre 2	FreeStyle Libre 3
Туре	rtCGM		isCGM	rtCGM
FDA approval	<u>></u> 2 yrs	> 2 yrs, pregnancy	<u>></u> 4 yrs, p	regnancy
Application site	Abdomen, upper buttocks (2-17 yrs)	Upper arm (7+ yrs), upper buttocks (2-6 yrs)	Upper arm	
Wear-time	10 days	10.5 days	14 days (soon to be 15 days)	
Transmitter	Reusable, 90 days	All-in-on, disposable	All-in-on, disposable	
Warm-up time	2 hours	30 minutes	1 hour	
Alerts	Real-time	Real-time, more customizable	Real-time	Real-time, more customizable
Water depth	8 feet, up to 24 hours		3 feet, up to	30 minutes
Calibration		Not neede	d, optional	
Interactions	Hydroxyurea		Vitan	nin C
Integration	Yes, multiple options	Not yet	Yes, multiple options	Not yet
MARD	9.0%	8.2%	9.2%	7.9%





FreeStyle Libre 2

- Senses values every 1 minute, but only displays when scanned* and *must* be scanned at least every 8 hours to record data
- Pairs with a smart phone via Bluetooth and/or a touchscreen reader
 - Must be within 20 feet of sensor
 - Compatible smart phones: <u>ART41556-102 rev-B-index (freestyleserver.com)</u>
 - Smart phone use requires applications
 - Libre 2 must always be running in the background and Bluetooth on
 - LibreLinkUp can share with up to 20 followers
 - Reader use requires USB plug-in to review data fully

*hold smartphone or reader within 1.5 inches from sensor

FreeStyle Libre 2

- Add "notes" (optional)
 - Insulin doses
 - Food
 - Finger-stick values
- Customize alerts + functions for enhanced discretion; however, value will *not* display until scanned
 - Sounds
 - Value thresholds

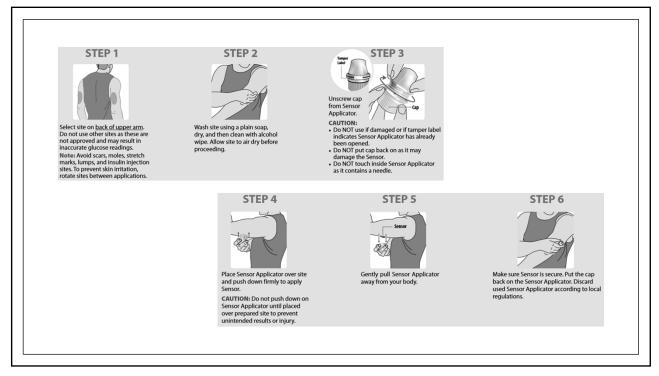




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	Dexcom G6	Dexcom G7	FreeStyle Libre 2	FreeStyle Libre 3
Туре	rtCGM		isCGM	rtCGM
FDA approval	≥ 2 yrs ≥ 2 yrs, pregnancy		≥ 4 yrs, pregnancy	
Application site	Abdomen, upper buttocks (2-17 yrs)	Upper arm (7+ yrs), upper buttocks (2-6 yrs)	Upper arm	
Wear-time	10 days	10.5 days	14 days (soon to be 15 days)	
Transmitter	Reusable, 90 days	All-in-on, disposable	All-in-on, disposable	
Warm-up time	2 hours	30 minutes	1 hc	our
Alerts	Real-time	Real-time, more customizable	Real-time	Real-time, more customizable
Water depth	8 feet, up to 24 hours		3 feet, up to	30 minutes
Calibration	Not needed, optional			
Interactions	Hydroxyurea		Vitam	nin C
Integration	Yes, multiple options	Not yet	Yes, multiple options	Not yet
MARD	9.0%	8.2%	9.2%	7.9%





FreeStyle Libre 3

- Senses/displays values every 1 minute (only requires scanning when pairing)
- Pairs with a smart phone via Bluetooth and/or a touchscreen reader (currently only available with DME companies and not yet retail pharmacies)
 - Must be within 33 feet of sensor
 - Compatible smart phones: https://freestyleserver.com/Payloads/IFU/2023/q1/ART44628-004 rev-H-web.pdf
 - Smart phone use requires applications
 - Libre 3 must always be running in the background and Bluetooth on
 - LibreLinkUp can share with up to 20 followers
 - Also compatible with Apple watch
 - Reader use requires USB plug-in to review data fully

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FreeStyle Libre 3

- Add "notes" (optional)
 - Insulin doses
 - Food
 - Finger-stick values
- Customize alerts + functions for enhanced discretion; values display always (no scanning needed)
 - Sounds
 - Value thresholds



Tips & Tricks for CGMs

Products for Extra Stickiness

0	Overbandage	A medical grade adhesive; bandage or tape [†]
Pura à	Tegaderm I.V. (overbandage)	A transparent film that provides adhesive strength
MARK SIM PR	Torbot skin tac	A hypoallergenic and latex-free "tacky" skin barrier
100 mg	Skin-prep protective barrier wipes	Protective liquid dressing that allows skin to breathe so tapes and films adhere better
	Mastisol liquid adhesive	Clear, non-irritating, non-water-soluble liquid adhesive that secures dressings even in moist areas

Products for Irritated Skin

Waterproof, breathable barrier film Also contains alcohol for antiseptic properties	Comes in wipes Let dry completely on skin Not marketed as having tackifying properties, but may see mild enhancement to adhesions
- Waterproof, breathable barrier film	- Comes in wipes or spray - Does not include antiseptic
- Vapor permeable barrier film - Includes antiseptic	- Comes in wipes - Can be used on damaged skin as protection
- Waterproof, breathable barrier film - Popular choice due to moderate protection and moderate adhesive properties combined*	Comes in wipes or spray Skin prep indicated for intact skin, no-sting skin prep indicated for intact or damaged skin Does not include antiseptic
- Waterproof, breathable barrier film	- Comes in wipes or spray - Does not include antiseptic
	film - Also contains alcohol for antiseptic properties - Waterproof, breathable barrier film - Vapor permeable barrier film - Includes antiseptic - Waterproof, breathable barrier film - Popular choice due to moderate protection and moderate adhesive properties combined* - Waterproof, breathable barrier

May prevent mild, moderate, and severe skin reactions due to CGM adhesive Fluticasone propionate nasal spray (generic). Common examples: - Flonase® Allergy Relief - Flonase® Children's Allergy Relief - Clarispray® Nasal Allergy Spray

Apply 2 puffs to sensor site. Wait 2 minutes for spray to dry. Insert sensor as usual.

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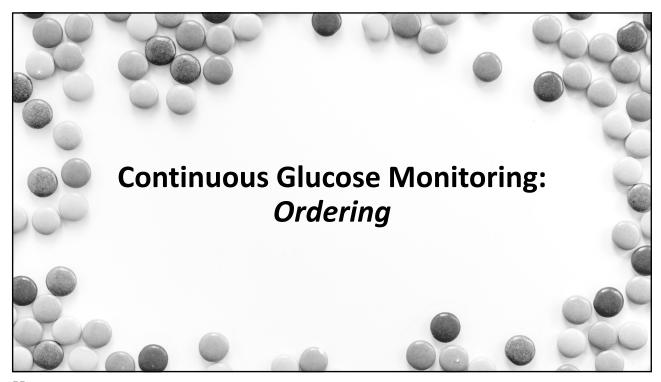
Customer Support & Application Videos

Dexcom

- Customer Support: Contact Dexcom Customer Service for CGM Assistance | Dexcom
- Dexcom G6 Application: Dexcom G6: How to Insert the Sensor & Attach the Transmitter | Dexcom Provider
- Dexcom G7 Application: How to Insert the Dexcom G7 Sensor [VIDEO] | **Dexcom Provider**

FreeStyle Libre

- Customer Support: Contact Us | Customer Care & Sensor Support FreeStyle Libre (CGM) systems
- FreeStyle Libre 2 Video: How to Apply the FreeStyle Libre 2 Sensor - YouTube
- FreeStyle Libre 3 Video: How to Set Up Your CGM System | FreeStyle Libre (CGM) systems



Ordering CGMs

CGM	Components	Quantity (3-month supply)	Refills
Dexcom G6	Dexcom G6 Sensor	9	3
	Dexcom G6 Transmitter	1	3
	Dexcom G6 Receiver	1, optional	0
Dexcom G7	Dexcom G7 Sensor/Transmitter	9	3
	Dexcom G7 Receiver	1, optional	0
FreeStyle Libre 2	Libre 2 Sensor	6	3
	Libre 2 Reader	1, optional	0
FreeStyle Libre 3	Libre 3 Sensor	6	3
	Libre Reader*	1, optional	0

*only currently available with DME suppliers

Ordering CGMs

- When should orders be sent to the pharmacy...
 - Medicaid
 - No prior authorization is required if insulin has been filled within the last 90 days
 - If not, the following prior authorization will be needed



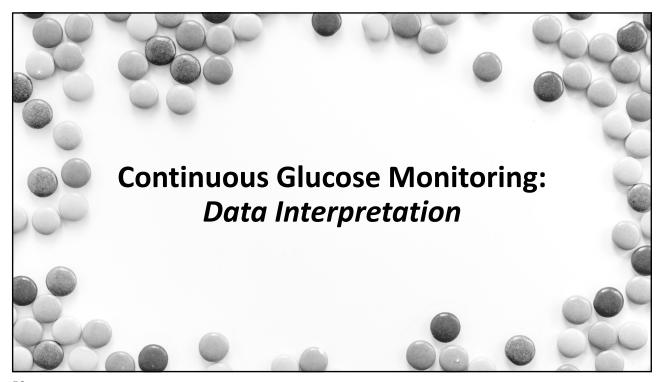
- Commercial plans
- · Paying out-of-pocket
- Some Medicare Advantage plans...

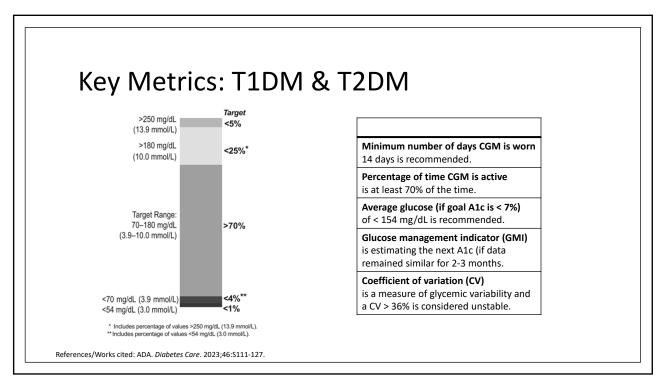
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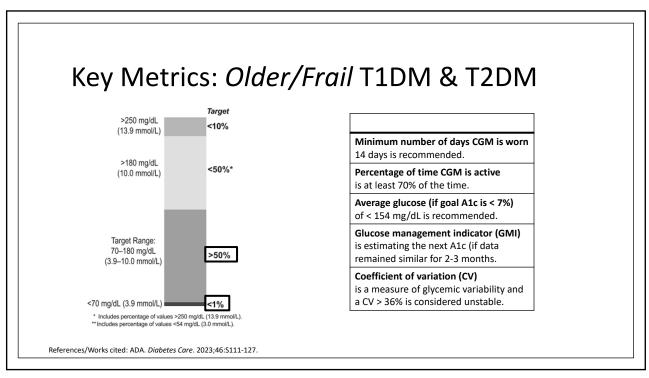
Ordering CGMs

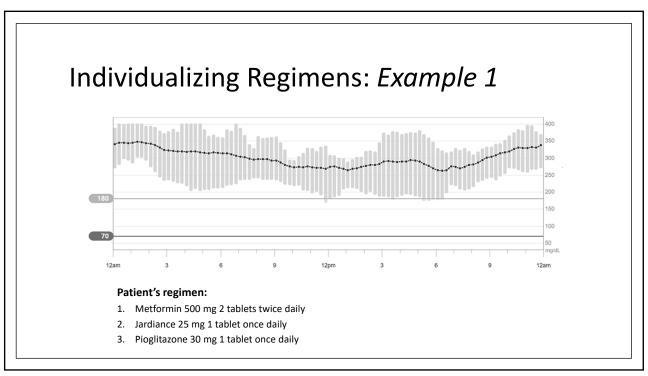
- When should orders be sent to a DME supplier...
 - Medicare plans
 - While some Medicare Advantage can be sent to the pharmacy, a DME company may ensure the lowest co-pay

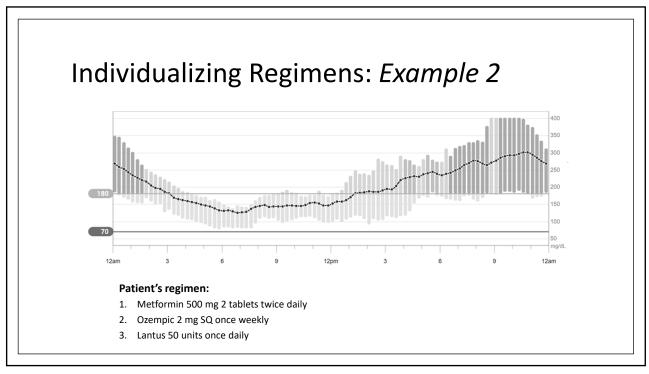


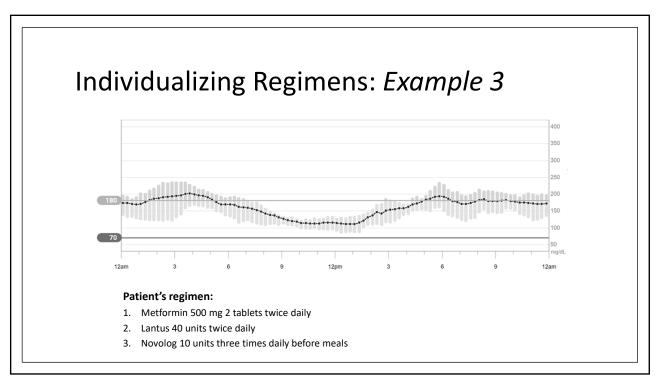


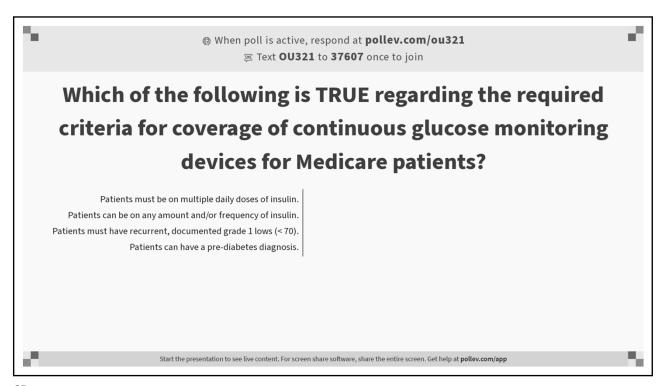


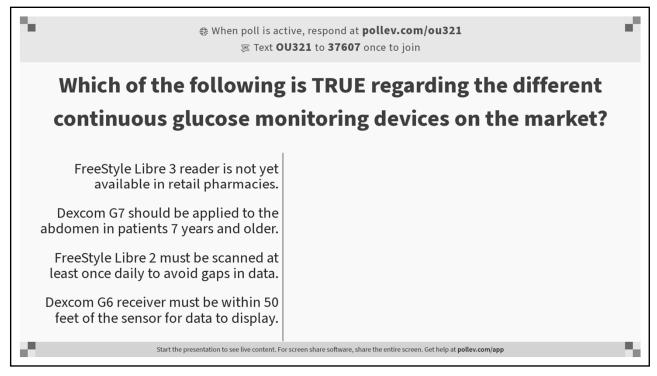


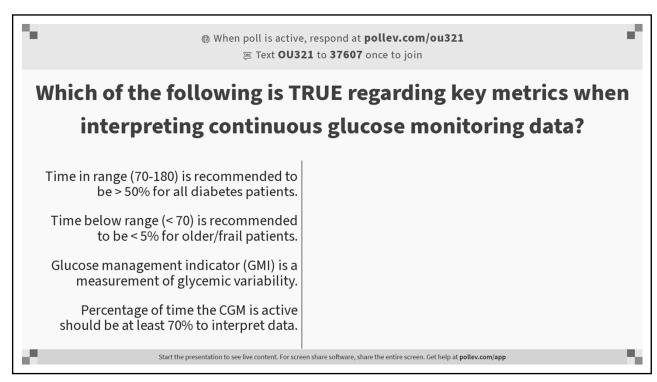












Conclusion and Clinical Pearls

- CGMs overcome many limitations of A1c and FSBG monitoring; evidence of improving glycemic control has more recently expanded to T2DM patients.
- Medicare and Medicaid criteria for CGM coverage recently changed to any "insulin-treated" patients or those with "problematic hypoglycemia."
- Key metrics and trends can be assessed to better personalize treatment regimens.
- There are several CGM products to consider for patients. Always keep in mind that "technology can either empower or burden patients".



Additional Resources

- Centers for Medicare & Medicaid Services (Updated 2023, February 23). Glucose Monitors. CMS.gov. <u>LCD - Glucose Monitors (L33822) (cms.gov)</u>.
- Dexcom. (2023). <u>Dexcom G7 CGM Powerfully simple diabetes management |</u> Dexcom.
- FreeStyle Libre. (2023). Continuous Glucose Monitoring (CGM) | FreeStyle Libre (CGM) systems.
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