



CGM

CONTINUOUS
GLUCOSE
MONITOR

Diabetes Technology: Continuous Glucose Monitor

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Disclosures

- The faculty listed below for this CE activity do not have any relevant financial relationship(s) with ineligible companies to disclose.

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- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.



Objectives

Assess differences between available CGMs and the appropriate patients and settings for implementing the use of diabetes technologies

Evaluate available evidence regarding the use of continuous glucose monitors in people with diabetes mellitus (DM).

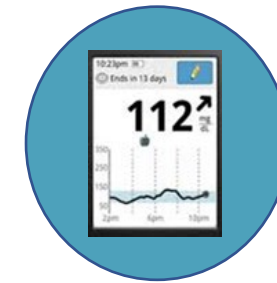
Develop a therapy plan to integrate diabetes technologies into clinical practice, identify interventions that can optimize time-in-range glucose values and harness these devices to improve glycemia in conjunction with standard of care.

Design a plan to educate and train the person with diabetes to ensure optimal diabetes technology use and empower patients to self-manage their diabetes

SMBG vs CGM



- SMBG
 - Measures capillary blood glucose
 - Provides sporadic data
 - Provides a snapshot of blood glucose at a single point in time
 - Can be burdensome for PWD



- CGM
 - Measures interstitial glucose
 - Provides real-time or retrospective blood glucose data
 - Provides insights into glucose trends so PWD can act preemptively to avoid hyperglycemia or hypoglycemia
 - Increased ease of use
 - Increased awareness of blood glucose levels

ADA. Diabetes Care. 2022;45:S1. Ajjan. Diabetes Technology & Therapeutics. 2017;19:S-27.
Longo. Diabetes Spectr. 2019;32:183.

CGM, continuous glucose monitoring; PWD, person/people with diabetes; SMBG, self-monitoring blood glucose.

Polling Question #1

- What is your baseline knowledge of CGM devices?
 - Very familiar with them, have initiated and currently see patients on device
 - Have heard of them and dispensed them from the pharmacy but have no knowledge of how they work
 - I use CGM
 - No knowledge



History of CGM

- 1999: First CGM approved; blinded 3-day sensor
- 2004: First CGM released for personal use by Medtronic
- 2006: First pump and CGM working together by Medtronic; first Dexcom available
- 2008: First Freestyle CGM available
- 2016-2017: First CGM that requires no calibration, Freestyle Libre; first hybrid-closed loop pump that adjusts insulin by Medtronic (670 g)
- 2024 – First OTC CGM



What is CGM?

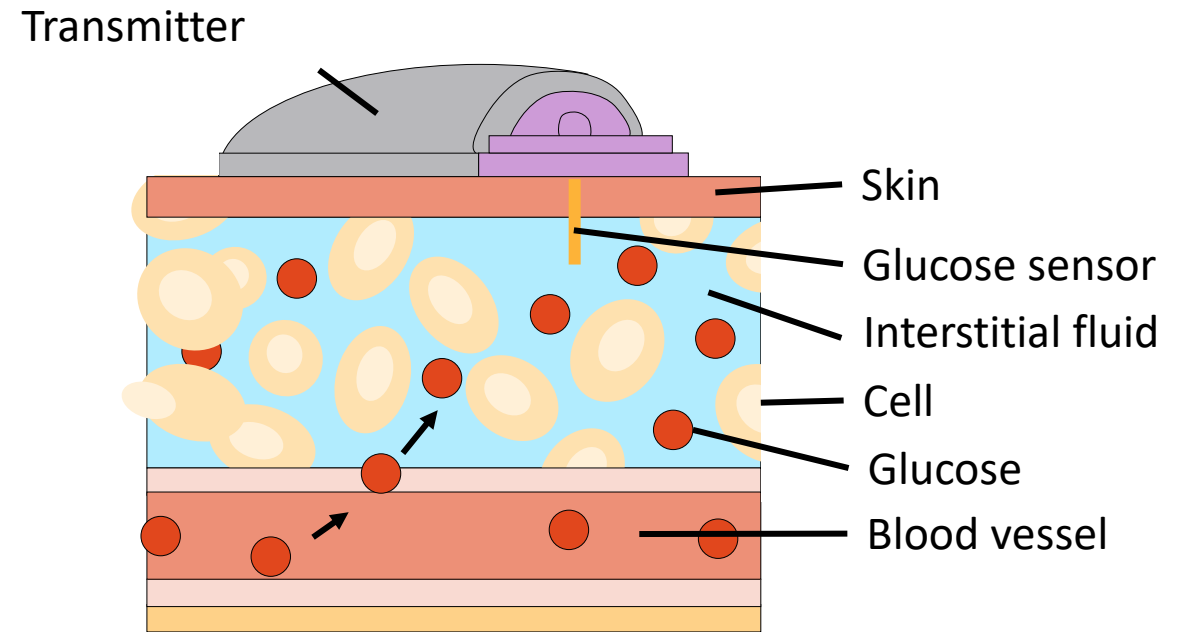


CGMs have three parts: sensor, transmitter, and receiver ((pump, phone, handheld receiver)

- CGM features vary slightly depending on the device
- A tiny glucose-sensing device called a "sensor" is inserted just under the skin and remains for 7–14 days
- A transmitter is attached to the sensor and sends the information to a receiver
- The receiver may be a manufacturer-issued display device, smart device, or insulin pump
- The system automatically records a glucose value every 1–5 minutes
- Some CGMs provide alarms to signal when glucose is out of target range

What does a CGM measure?

- Sensor measures glucose levels in **interstitial fluid**, whereas blood glucose meters measure glucose in **blood**
- CGM leads to fewer highs and fewer lows
- CGM measures interstitial glucose, meaning the glucose concentration in the fluid just under the skin
- This may lag 5-15 minutes behind the blood glucose
- This may lead to some discrepancies between CGM readings and fingerstick readings, particularly if the glucose is changing rapidly
- Current CGMs on the market have a high degree of accuracy based upon available data



Polling Question #2

• **Have you implemented a CGM device and/or sold and/or educated a patient?**

Yes we have it on formulary at my organization

Yes, we stock it in my pharmacy

Yes, I provide Medication Therapy Management (MTM) that includes monitoring of patients on CGM

No, have no implemented, dispensed or educated a patient on device

Other



Why is CGM Used?



- Can uncover undetected hypoglycemia and other glucose trends. Possible verification with finger-stick may be warranted.
- Can provide direction and rate of change of glucose
- Can provide alerts if glucose is or is predicted to be outside target range
- Can contribute to improved glucose control and detecting the impact of food, activities and behavior on glycemia
- Ongoing use is recommended to maximize benefits
- May pair with select insulin pumps for automated insulin delivery systems
- Can reduce the number of fingersticks

CGM metrics for clinical decision

- Established clinical targets to individualize glycemic targets and adjust therapy based on each individual’s overall health status, concomitant medical condition (eg, pregnancy, frailty), and risk for hypoglycemia:
- **All Persons with Diabetes**
 - Number of days of active CGM use: 14 days preferred
 - Percentage of data available from active CGM use: >70% of data from 14 days
 - Mean glucose: Individualized to targets
 - Glucose management indicator (GMI): Individualized to targets
 - Glycemic variability, percent coefficient of variation (%CV [coefficient of variation]): $\leq 36\%$
- Two metrics, %TIR and %TBR, should be used as a starting point for the assessment of quality of glycemic control and as the basis for therapy adjustment, with emphasis on reducing %TBR when the percentages of CGM values falling below 54 mg/dL or 70 mg/dL are close to or exceed targets.

Standardized Metrics for CGM Data Interpretation

Key Metric	Measure
Number of days CGM is worn	14 days
Percentage of time CGM is active	Recommend > 70% wear time over 14 days
Mean glucose	Average glucose over the wear period
Glucose management indicator	CGM version of estimated A1C
Glycemic variability (coefficient of variation)	Standard deviation/mean, stable $\leq 36\%$
TAR level 2	% readings and time >250 mg/dL
TAR level 1	% readings and time 181–250 mg/dL
TIR	% readings and time 70–180 mg/dL
TBR level 1	% readings and time 54–69 mg/dL
TBR level 2	% readings and time <54 mg/dL

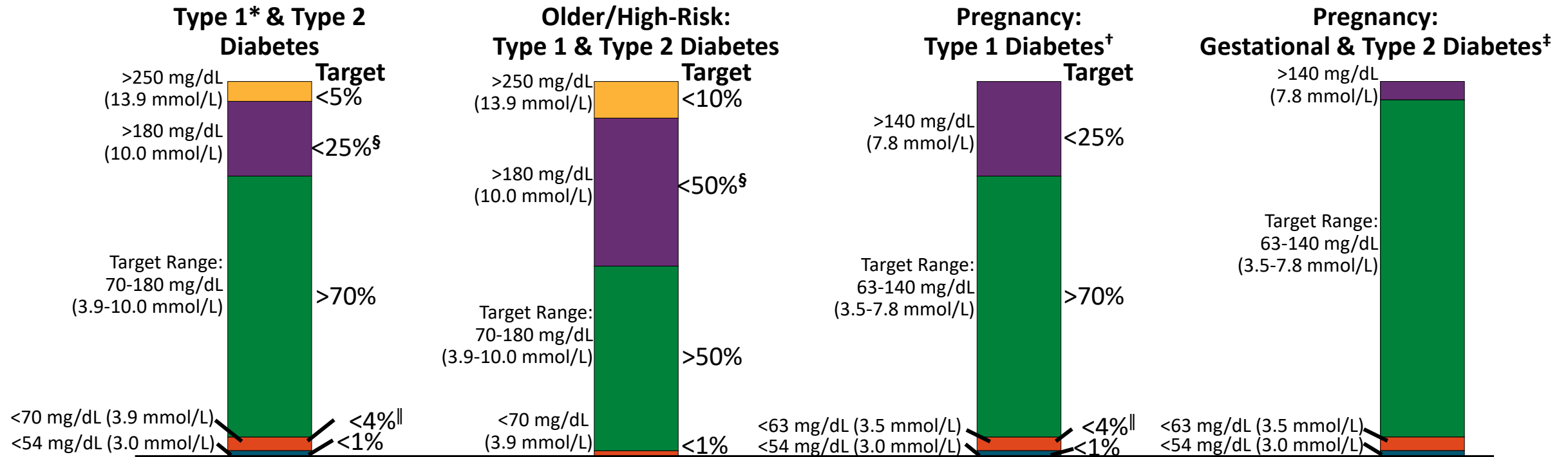
TAR = time above range; TBR = time below range; TIR = time in range.

Time in Range

- **Time in range:** Duration of patient's blood glucose within individual's target range (70-180 mg/dL)
- Also important to interpret **time below and time above target range**
- Meaningful indicator of glycemic control during shorter evaluation periods (< 2-3 mos)
- Easy for patient to understand and control

A1C Testing	Time in Range
Evaluates a single A1C level	Evaluates continuous glucose levels
A1C levels compared 3 mos apart	Compares glucose fluctuations for any amount of time
Does not capture same-day hypoglycemic or hyperglycemic levels	Captures all glucose levels and identifies time it is within a safe range
Less likely to capture impact of acute interventions	Likely to capture impact of acute interventions

Different Populations Have Different Targets



*For age <25 yr, if the A1C goal is 7.5%, then set TIR target to approximately 60%. (See *Clinical Applications of Time in Ranges* section in the text for additional information regarding target goal setting in pediatric management.)

[†]Percentages of time in ranges are based on limited evidence. More research is needed.

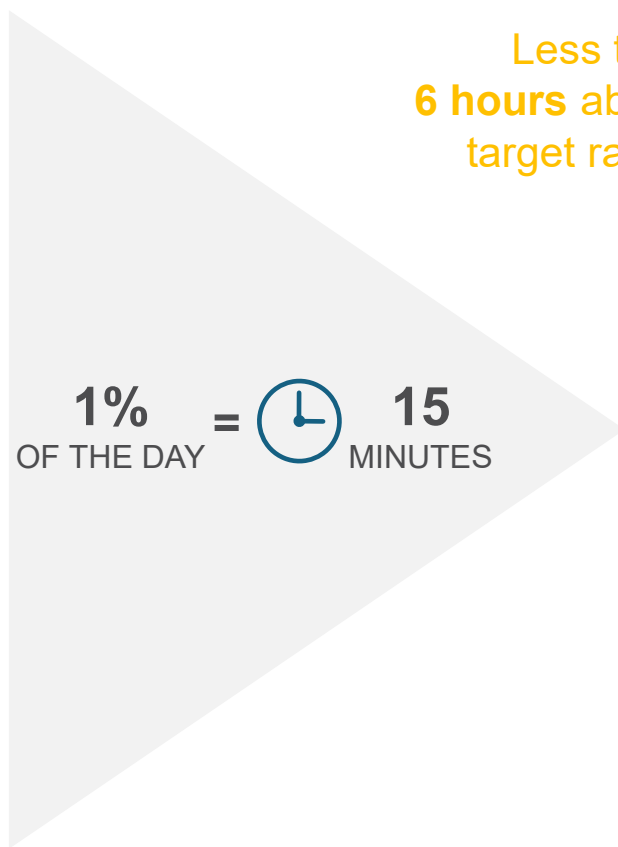
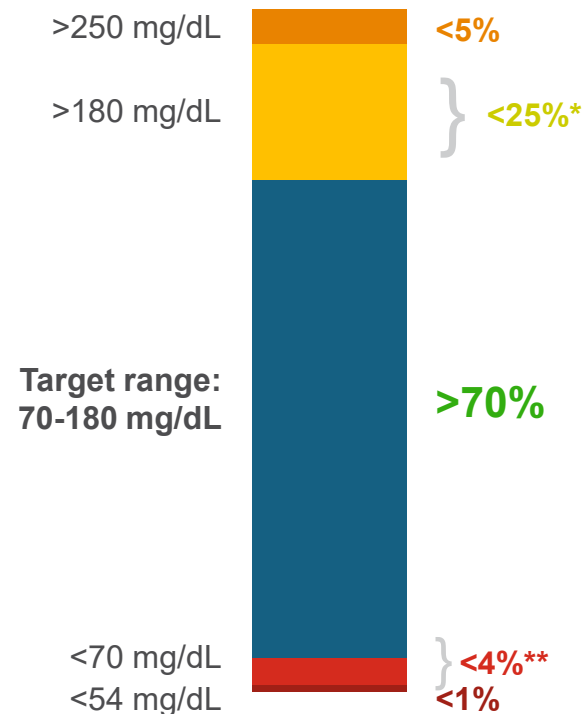
[‡]Percentages of time in ranges have not been included because there is very limited evidence in this area. More research is needed. Please see *Pregnancy* section in text for more considerations on targets for these groups.

[§]Includes percentage of values >250 mg/dL (13.9 mmol/L).

^{||}Includes percentage of values >54 mg/dL (3.0 mmol/L).

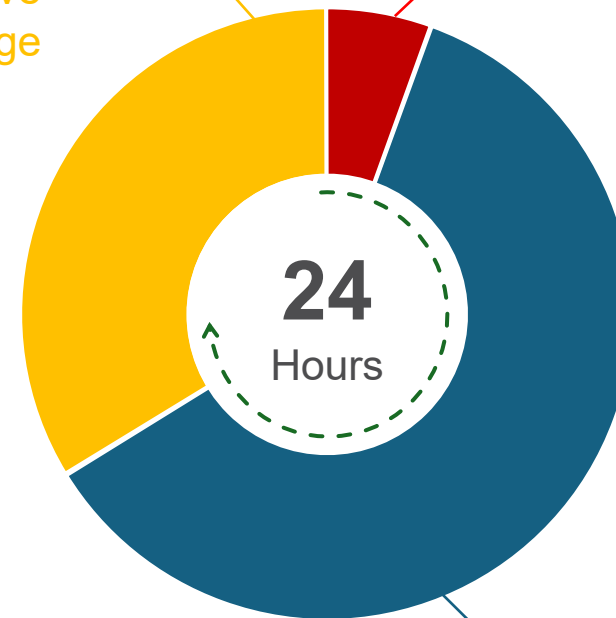
Time in Range (TIR) targets and hours per day^{1,2}

Recommended Time in Range for most people with T1D & T2D¹



Less than 6 hours above target range

Less than 1 hour below target range



At least 17 hours in target range

1. ADA. *Diabetes Care*. 2023;46(Suppl 1):S111-S127

CGM Device Definitions

CGM	Description
Real-time CGM	measure and display glucose levels continuously. Provides automated alerts at specific and/or changing glucose levels
Intermittently scanned CGM (isCGM) with and without alarms	measure glucose levels continuously but require scanning for visualization and storage of glucose values
Blinded CGM	Displays glucose values in clinic only (initiated in a clinic using a reader owned by the clinic)
Unblinded CGM	Displays glucose values to patient

Types of CGM Systems

Characteristic	Professional CGM	Personal CGM
Owner	Clinic	Patient
Feedback	Blinded and unblinded (real-time feedback) options	Real-time feedback or scan for feedback (flash device)
Use	Short term (7-14 days)	Long term (≥ 14 days)
Insurance coverage	Most people with T1D or T2D	Patients on any insulin therapy
Compatibility	Not compatible with insulin pumps	Some devices compatible with smartphones and insulin pumps
Summary	owned and applied in the clinic, and provide data that are blinded or unblinded for a discrete period of time	unblinded and intended for frequent/continuous use, including real-time CGM (rtCGM) and intermittently scanned CGM (isCGM)

The types of sensors currently available are either disposable (rtCGM and isCGM) or implantable (rtCGM).



Real-Time CGM

Measurement

- Glucose measurement in interstitial fluid
 - Parallels BG values
- Complete glucose profiles are given
- Current BG value plus trend

Reporting

- Sensor sends data in real time to monitor
 - Alarms for warning when BG is too high/low
- Interpretation of BG data requires experience and substantial education



Intermittently Scanned (Flash) Glucose Monitoring

Measurement

- Glucose measurement in interstitial fluid
- User receives 8-hr glucose profile, current BG value plus trend after active scanning of the sensor
- Current BG value plus trend

Reporting

- Some recent devices include alarms to warn when BG is too high/low
- Therapeutic decision is possible based on measured values
- Interpretation of BG data requires experience and moderate education

Current Options for Professional CGM Systems

CGM devices that are placed on the person with diabetes in the health care professional's office (or with remote instruction) and worn for a discrete period of time (generally 7–14 days). Data may be blinded or visible to the person wearing the device. The data are used to assess glycemic patterns and trends. Unlike rtCGM and isCGM devices, these devices are clinic-based and not owned by the person with diabetes.

Dexcom G6 Pro



FreeStyle Libre Pro



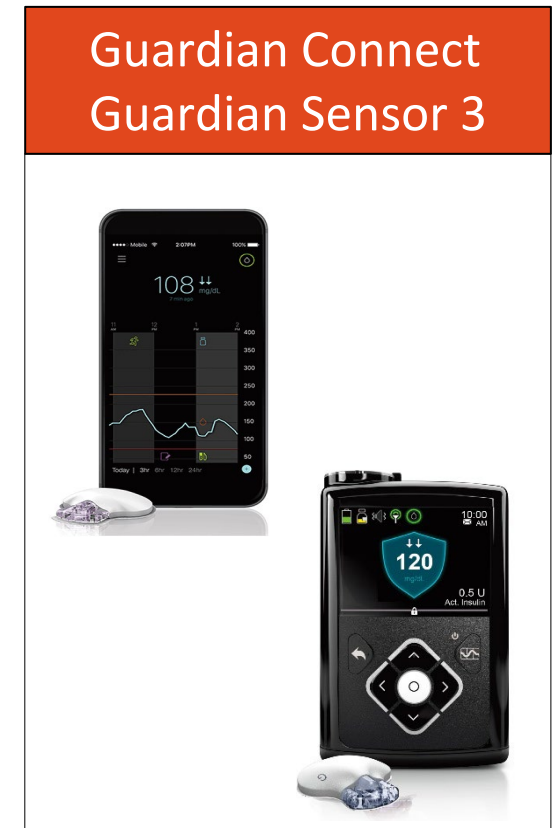
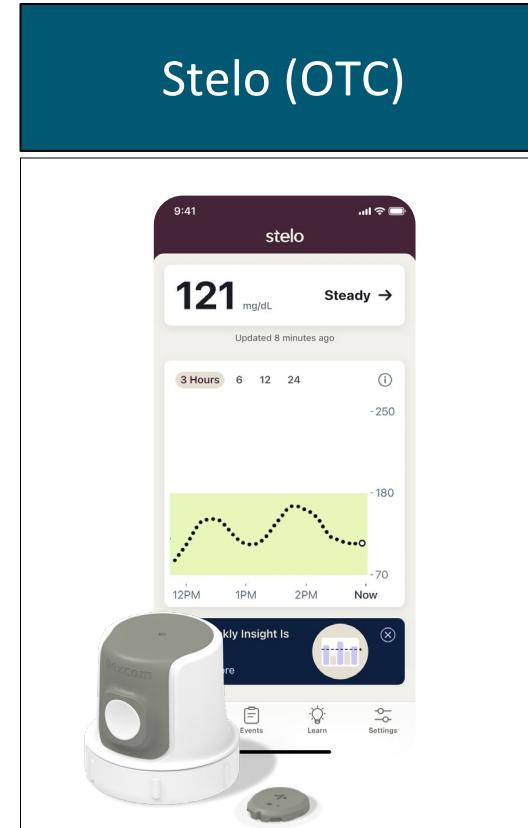
Comparison of Professional CGM Systems

Features	Abbott FreeStyle Libre Pro	Dexcom G6 Pro
Approved ages	≥ 18 yrs	≥ 2 yrs
Warm up time	1 hr	2 hr
Frequency of glucose readings	Glucose readings sent to receiver/ smart device every 5 mins	Records glucose q15 mins
Insertion	Single-step process with auto-inserter	2-step process: inserting sensor and attaching transmitter
Body site with FDA approval	Back of upper arm	Abdomen (also, upper buttocks for patients 2-17 yrs)
Alarm for high/low glucose	No	Yes (unblinded)

Comparison of Professional CGM Systems

Features	Abbott FreeStyle Libre Pro	Dexcom G6 Pro
Blinded or unblinded	Blinded	Blinded and Unblinded
Maximum wear time	14 days	10 days
Calibrations	None required	None required
Components	Combined disposable sensor/transmitter Touchscreen reader device, owned by clinic	Disposable sensor and disposable/transmitter Touchscreen reader device, owned by clinic
Care between use	None, disposable	None, disposable
MARD; mean absolute relative difference	12.30%	9.00%
Interfering substances	Salicylic acid and high-dose vitamin C	Hydroxyurea; acetaminophen >4 g
Systems for downloading data and reports	LibreView	CLARITY

Current Options for Personal CGM Systems



Dexcom G6 available but being phased out

Stelo available online for ordering via Abbott. Not currently in pharmacies

Current Options for Personal CGM Systems

FreeStyle Libre 14
(Flash)



Abbott Freestyle Libre
2



Abbott FreeStyle Libre
3



Eversense





Case Study

- 34-yr-old female
 - Type 1 diabetes, ESRD on dialysis, workup for renal transplant
 - Hypoglycemia unawareness, multiple episodes of severe hypoglycemia resulting in unconsciousness and EMS treatment
 - Lives with 4-yr-old son; no other adults in the house
 - Prescribed Dexcom; using with smartphone
 - Dexcom is not FDA approved for patients on hemodialysis
 - Results sent to family member who ensures safety and is alerted when patient is having a low
-

Comparison of Personal CGM Systems

Features	Dexcom G6	Dexcom G7	Stelo	FreeStyle Libre 14	FreeStyle Libre 2	FreeStyle Libre 3 & sensor 3 plus	Guardian Connect & Sensor 3	Eversense
CGM Type	rtCGM	rtCGM	rtCGM	isCGM	isCGM	rtCGM	rtCGM	rtCGM
Real time alarm	Yes	Yes	Yes	No; trend arrow	Yes	Yes	Yes	Yes
Receiver (display device)	Smartphone or Reader	Smartphone or Reader	Smartphone	Smartphone or Reader	Smartphone or Reader	Smartphone	Smartphone	Smartphone
FDA approved, ages (yrs)	≥2	≥2	≥18	≥18	≥4	≥2	Guardian 3: > 2 Guardian Connect: 14-75	≥18
Maximum wear time	10 days	10 days	15 days	14 days	14 days	15 days	7 days	180 days
Warm-up time	2 hrs	30 mins	30 mins	1 hr	1 hr	1 hr	≤ 2 hrs	≤ 24 hrs
Calibrations	None;optional	None	None	None	None	None	2-4/day	BID x 3wk; then daily
Frequency of glucose reading	Q5mins	Q5mins	Q15mins	Q1min; records q15mins	Q1min; records q15mins	Q1min	Q5mins	Q5mins

1. AADE Practice Paper, 2018. 2. <https://www.dexcom.com/safety-information>. 3. <https://www.freestylelibre.us/#safety-information>. 4. <https://www.freestylelibre.co.uk/libre/discover/diabetes-management-pregnancy.html>. 5. <https://www.medtronicdiabetes.com/important-safety-information>. 6. <https://www.eversenseddiabetes.com/safety-info>. 6 <https://support.levels.com/article/492-about-the-dexcom-stelo>

Comparison of Personal CGM Systems

Features	Dexcom G6	Dexcom G7	Stelo	FreeStyle Libre 14	FreeStyle Libre 2	FreeStyle Libre 3 & sensor 3+	Guardian Connect & Sensor 3	Eversense
Body site with FDA approval	Abdomen, buttocks (pediatrics)	Back of upper arm, buttocks (pediatrics)	Back of upper arm	Back of Upper Arm	Back of Upper Arm	Back of Upper Arm	Abdomen or back of upper arm	Back of upper arm
FDA approved for insulin dosing	Yes	Yes	No	Yes	Yes	Yes	No	Yes
Insulin pump integration	Yes, Omnipod 5, T: Slim X2		No	No	No	No	Yes; Minimed 770G, 670G pump	No
MARD	9.0%	8.2%	8.3%	9.4%	9.2%	7.9%	9.64%	8.5%
Use in pregnancy	No	Yes	No	US: not approved UK: approved	Yes	Yes	Not studied ^[5]	Not tested ^[6]
Available applications	Dexcom G6, Dexcom CLARITY, Dexcom Follow	Dexcom G7 app, Dexcom CLARITY, Dexcom Follow	Stelo by Dexcom App	Libre Link, Libre Link Up	LibreLink2, LibreLinkUp	LibreLink3, LibreLinkUp	Guardian Connect, CareLink	Eversense App, Eversense NOW
Compatible software	Dexcom CLARITY, Glooko, Tidepool	Dexcom CLARITY, Glooko, Tidepool	Dexcom CLARITY	LibreView, Tidepool	LibreView, Tidepool	LibreView, Tidepool	CareLink, Tidepool	Eversense Data Management System, Glooko

Interfering Substances

Systems affected	Medication	Effect
Dexcom G6 and Dexcom G7	Acetaminophen >4 g/day Hydroxyurea	Higher sensor readings than actual glucose
Medtronic Guardian	Acetaminophen - Any dose Alcohol Hydroxyurea	Higher sensor readings than actual glucose
FreeStyle Libre	Ascorbic acid (vitamin C), >500 mg/day Mannitol	Higher sensor readings than actual glucose
Senseonics Eversense	Tetracycline	Sensor bias within therapeutic concentration ranges

Enhance diabetes management with CGM

Most accurate¹



dexcom G7



30-minute warmup²

Real-time and retrospective glucose information²



Fully disposable with 12-hour grace period to change sensor²

Actionable alerts²



Integrated sensor/transmitter²

Remote monitoring²



Painless insertion^{2,*}

Real-time CGM cleared for use with AID system²



No limitations for use during pregnancy

Dexcom G7 components and app



Applicator

Contains an all-in-one disposable wearable with painless[§] and simple insertion¹



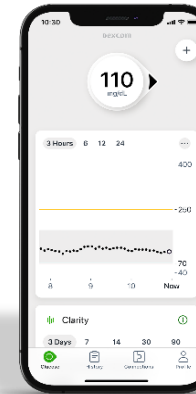
Sensor

Smaller sensor with integrated, single-use transmitter¹



G7 Receiver

Redesigned optional[‡] receiver that is smaller with a more vibrant, easy-to-read display^{1,2}



G7 App

Intuitive app design with simplified onboarding and customizable options to make alerts discreet and actionable^{1,2,†}



Watch

G7 is the first and only CGM to connect directly to your compatible Apple Watch*

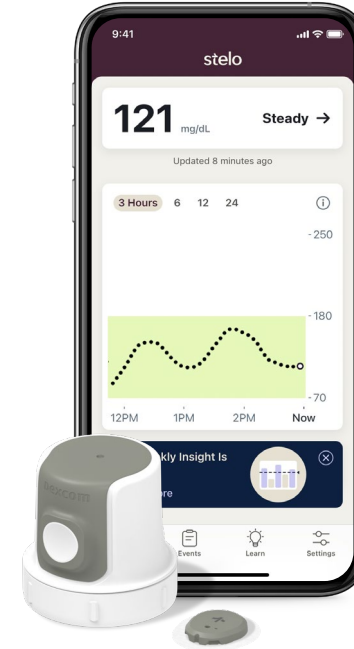
Dexcom G7

stelo

Dexcom G7*

For people with diabetes ages 2 years and older who want¹:

- ✓ to replace the use of fingersticks to make treatment decisions[‡]
- ✓ to **detect hyperglycemia/hypoglycemia** and receive **actionable alerts**
- ✓ to **share glucose data** with family and/or caretakers[§]
- ✓ autonomous communication with **digitally connected devices**, including Direct to Watch^{||,3} and AID systems



Stelo†

For adults with prediabetes or T2D **not on insulin** who want²:

- ✓ to **improve their health**
- ✓ to **understand** how lifestyle and behavior modifications—including food, drink, physical activity, stress, and sleep—impact glycemic wellness
- ✓ education, **glucose insights**, and nudges
- ✓ support **following diagnosis**

A portfolio fit for purpose.

Products built for the people who use them.



Application Site

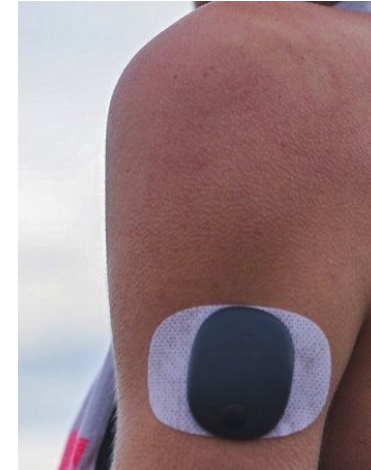


Guardian connect



Freestyle Libre 14

- FDA approved for insulin dosing, except during the first 12 hrs after insertion
- Must scan every 8 hrs to avoid data gaps

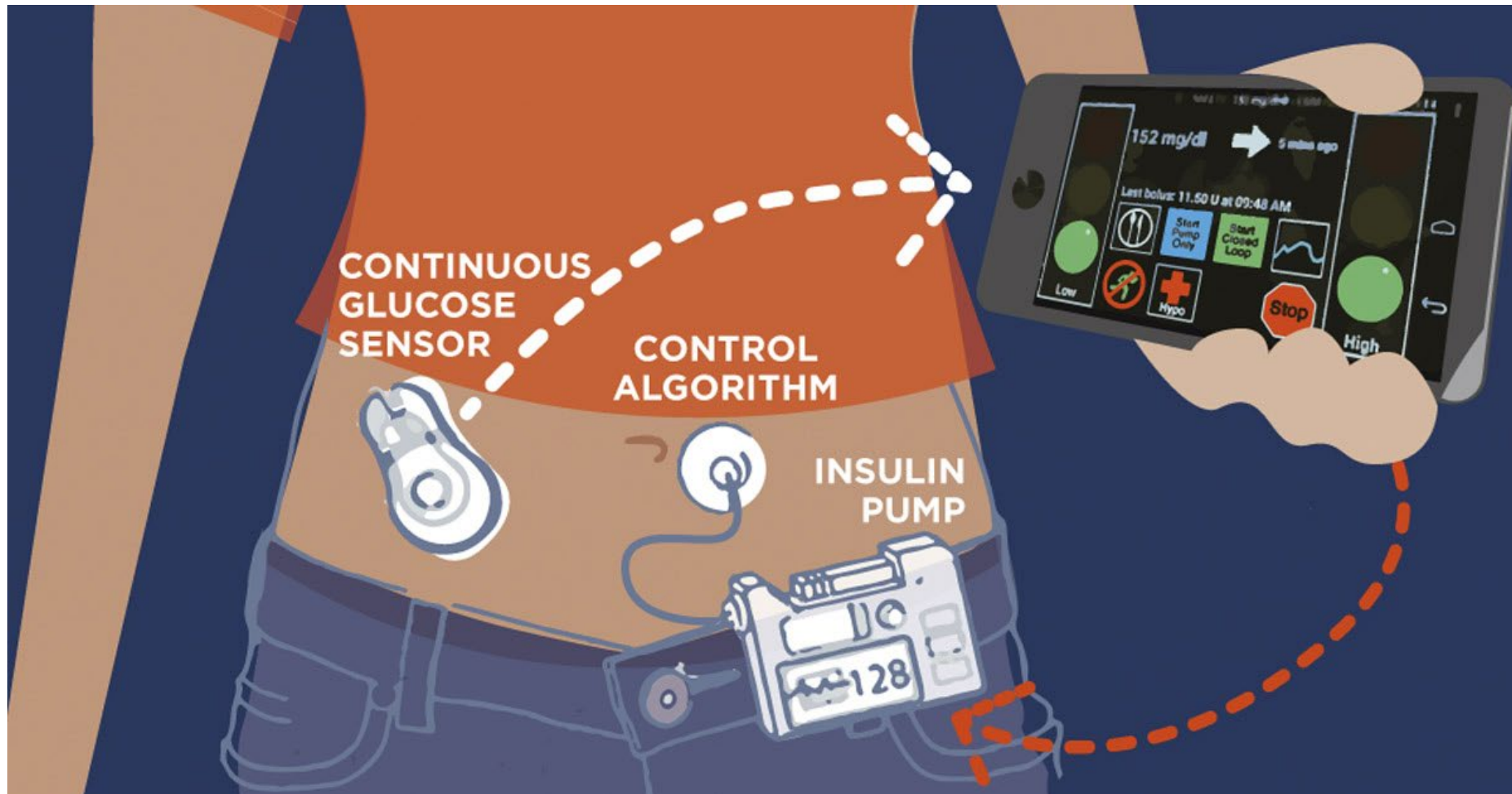


Eversense



- Implantable CGM, MRI safe

SAP and Closed-Loop Therapy → Goal for All Patients



Site Adhesiveness

- Contact dermatitis—both irritant and allergic—has been reported with all devices that attach to the skin. In some cases, this dermatitis has been linked to the presence of isobornyl acrylate, which is a skin sensitizer and can cause an additional spreading allergic reaction. Patch testing can be performed to identify the cause of the contact dermatitis in some cases. Identifying and eliminating tape allergens is important to ensure comfortable use of devices and to enhance patient adherence. In some instances, use of an implanted sensor can help avoid skin reactions in patients who are sensitive to tape.
- Rotating body sites is important between applications, as well as considering sleeping positions, exercise routines, and clothing. Sensors should be placed on clean dry skin, avoiding placement on broken or irritated skin. It may be necessary to shave areas to improve placement in some individuals. Patients should be counseled to avoid placement of CGM on wet skin immediately after a shower or bath. Also, to prevent sweating, unscented antiperspirant can be applied before sensor application has also been shown to prevent skin irritation or itchiness (Messer 2018).
- Several products are available to aid in adhesiveness. Skin-Tac or Skin-Prep can be applied to the skin before sensor application to aid in adhesion. Other overlap products may be applied after sensor placement, such as Simpatch or Tegaderm. Persons with diabetes can be directed to the individual CGM websites for resources to improve adhesion, including those for Dexcom, Abbott, and Medtronic.

<https://www.medtronicdiabetes.com/sites/default/files/library/download-library/workbooks/Tape%20Tips%20and%20Site%20Management.pdf>

Landmark Trials for CGM

Trial	Population	Intervention	Findings
DIAMOND ^[1]	T1D (using MDI)	CGM	Significantly greater decrease in A1C vs usual care
GOLD ^[2]	T1D (using MDI and A1C > 7.5%)	CGM	Improved glycemic control vs conventional treatment
IMPACT ^[3]	Well controlled T1D	Flash CGM	Reduced time in hypoglycemia
REPLACE ^[4]	T2D, on intensive insulin therapy	Flash CGM	Sustained reduction in hypoglycemia, No change in time in range
CONCEPTT ^[5]	T1D, pregnant or planning pregnancy	CGM	More time in target, less time hyperglycemic; Neonatal health outcomes significantly improved
COMISAIR ^[6]	T1D (A1C 7%-10%)	SAIR	Decrease in A1C and hypoglycemia, with sensor-augmented insulin regimen (SAIR)

1. Beck. JAMA. 2017;317:371. 2. Lind. JAMA. 2017;317:379. 3. Bolinder. Lancet. 2016;388:2254.

4. Haak T. Diabetes Ther. 2017;8:55. 5. Feig. Lancet. 2017;390:2347. 6. Soupal. Diabetes Technol Ther. 2016;18(9):532.

Lessons Learned From CGM Clinical Trials

- It is difficult to achieve glycemic goals with fingersticks alone
- Use of CGM substantially improves glycemic control without increasing hypoglycemia + Fear of hypoglycemia and lack of understanding about glycemic excursions keep patients from adjusting insulin dose appropriately in many instances
 - - CGM helps reduce A1c without increasing hypoglycemia
- Consistency of use on a daily basis is the most important factor for success with CGM
- Patients with both high and low A1c values obtain clinical benefit from use of CGM

Lessons Learned From CGM Clinical Trials

- SMBG is done sporadically and has limited patient acceptance
- rtCGM has a high level of acceptance and enables actions on predicted glucose levels in a much safer way
- To make the right treatment decisions a high level of accuracy has to be guaranteed (especially in the low glucose range)
- Only rtCGM has the potential for treatment automatization regarding glucose homeostasis leading to semi-"closed loop

Polling Question #3

- **What criteria do you follow when choosing a CGM device. (select all that apply)**
 - ADA guidelines – all patients on insulin therapy
 - AACE guidelines – for selected patients
 - Only patients who can afford device regardless of guidelines recommendation
 - If I get it free from the manufacturer

Indications for CGM Therapy

International Consensus:¹

- All patients with T1D
- T2D treated with intensive insulin therapy, not meeting glycemic goals
- Those with problematic hypoglycemia

American Diabetes Association:²

- Type 1 diabetes, type 2 diabetes on any insulin therapy – basal only, multiple daily injections or insulin pump

AACE:³

- ALL persons with diabetes treated with intensive insulin therapy, defined as 3 or more injections of insulin per day or the use of an insulin pump.
- ALL individuals with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness).
- Children/adolescents with T1D.
- Pregnant women with T1D and T2D treated with intensive insulin therapy.
- Women with gestational diabetes mellitus (GDM) on insulin therapy.
- *May be* recommended for women with GDM who are not on insulin therapy.
- *May be* recommended for individuals with T2D who are treated with less intensive insulin therapy.

1. Danne et al. *Diabetes Care* 2017; 40:1631-1640.

2. ADA. *Diabetes Care*. 2023;46(Suppl 1):S111-S127.

3. AACE 2021. *Endocrine Practice*, Volume 27, Issue 6, 505 - 537.



Patient Selection: Other Populations

■ **Pregnancy**

- ADA recommends real-time CGM for pregnant women with T1D to improve A1C levels, time in range, and neonatal outcomes^[1]
- In CONCEPTT trial, CGM during pregnancy significantly decreased incidence of LGA, neonatal hypoglycemia, and NICU admissions^[2]

■ **Individuals at risk of hypoglycemia**

- CGM may help identify hypoglycemia in elderly patients and in those with hypoglycemia unawareness^[3]



Role of CGM in Managing PPG

- CGM allows patients to view how and when PPG is affected by different meal types, behaviors, exercise, and medications
 - Insight into insulin absorption
 - Insulin timing and dose can be adjusted based on glucose readings and trend arrow data
- Real-time data from CGM allows the assessment of glucose fluctuations, degree/duration of PPG excursions, and specific PPG profiles
- CGM data can support discussions regarding dietary composition and dosing calculations during patient counseling

Polling Question #4

- **Which of the following best represents your experience of payer coverage determinations related to CGM? (select all that apply)**
- Most of my payers pay for only test strips
- Most of my payers prefer CGMs
- Most of my payers prefer CGMs, but not a specific product
- Most of my payers have placed the test strip and CGMs at parity

CGM Qualifying Criteria

- CGM: Type 1 diabetes, type 2 diabetes on any insulin therapy – basal only, multiple daily injections or insulin pump
- Diagnosis codes are important

Commercial Plans	Medicare 2023 ¹	Medicaid ²
<ul style="list-style-type: none">■ Plan specific, more flexibility■ Coverage often through pharmacy vs DME companies	<ul style="list-style-type: none">■ Have diabetes■ Treated with insulin AND seen for diabetes management in the past 6 months■ Not treated with insulin AND has documentation in medical record of 2 or more episodes of hypoglycemia (<54 mg/dL) despite multiple efforts to adjust medications/treatment plans AND seen for diabetes management in the past 6 month	<ul style="list-style-type: none">■ Similar to Medicare with a few plan-specific exceptions■ Self-monitoring of blood glucose at least three times per day■ Regular visits with an endocrinologist or other healthcare provider■ Some plans require either documented hypoglycemia unawareness or evidence of multiple severe low BGs (<50 mg/dL)

CGM Is Billable

- Interpretation of CGM is billable with CPT code 95251
- CPT codes 95250, 95251, 95249 require a minimum of 72 hrs of data
- Can only be reported once per month per patient

CPT Code	Description
95250/ 95249	<ul style="list-style-type: none">■ Sensor placement■ Hook-up and calibration■ Patient training■ Sensor removal (professional CGM only)■ Printout of recording
95251	<ul style="list-style-type: none">■ Analysis■ Interpretation■ Report



When is one method of CGM preferred over the other?

- Clinicians should prescribe CGM as a tool to track glucose before, during, and after exercise in persons with diabetes; monitor the glycemic response to exercise; and help direct insulin and carbohydrate consumption to avoid hypoglycemia and hyperglycemia. When this technology is utilized as part of AID systems, it can reduce glycemic excursions during exercise.
- Real time CGM (RT-CGM) is recommended for persons ≥ 65 years old with insulin-requiring diabetes to achieve improved glycemic control, reduce episodes of severe hypoglycemia, and improve quality of life (QoL).
- RT-CGM should be recommended over Intermittently scanned (IS-CGM) to persons with diabetes with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness) who require predictive alarms/alerts; however, the lifestyle of the person with diabetes and other factors should also be considered.



When RT-CGM may be preferred:

- For persons with diabetes who are physically active or have busy lifestyles that would inhibit frequent scanning of an IS-CGM sensor
- Require uninterrupted monitoring by parents/caregivers
- Choose to use advanced insulin delivery technologies (sensor augmented pump or automated insulin delivery system)
- Cannot achieve desired glycemic targets with IS-CGM.^{2,3}



When IS-CGM should be considered

- Newly diagnosed with T2D
- Treated with non-hypoglycemic therapies
- Motivated to scan device several times per day
- At low risk for hypoglycemia, although desire more data than SMBG provides.



When Professional CGM should be considered

- Newly diagnosed with diabetes
- Not using CGM
- May have problematic hypoglycemia, but no access to personal CGM
- Persons with T2D treated with non-insulin therapies who would benefit from episodic use of CGM as an educational tool
- Persons who would like to learn more about CGM before committing to daily use.



ADA – Choosing a CGM

- Take the time to investigate both options and talk to your doctor and diabetes educator, who can provide valuable guidance and insights about the type of CGM system that may be right for you.
- They can also help you make the transition to a CGM and provide training to help you learn how to interpret and use your data to make appropriate treatment decisions and achieve your blood sugar goals.



ADA – Choosing a CGM


Real time CGMs

Pros

1. **Offers alerts.** most significant benefit is having audible alarms which allows time for adjustments
2. **Transmits data continuously.**
3. **Shares data.** with family members and friends and acts as a safety net
4. **Eliminates finger sticks.** not all real-time CGMs offer this benefit, but some allow treatment decisions—how much insulin to dose —without the need for finger-stick confirmation.
5. **No calibration** eliminating the hassle and pain of calibrating with finger sticks

Cons

1. **Requires setup.** can get a little complicated especially if do not read instruction or no education provided
2. **Alerts can be tiresome.** Some people complain about the repeated alarms (real or false).
3. **Devices can be expensive.** covered by most insurance companies and Medicare, they may not be affordable if you have to pay out of pocket. Many device manufacturers offer patient assistance programs.

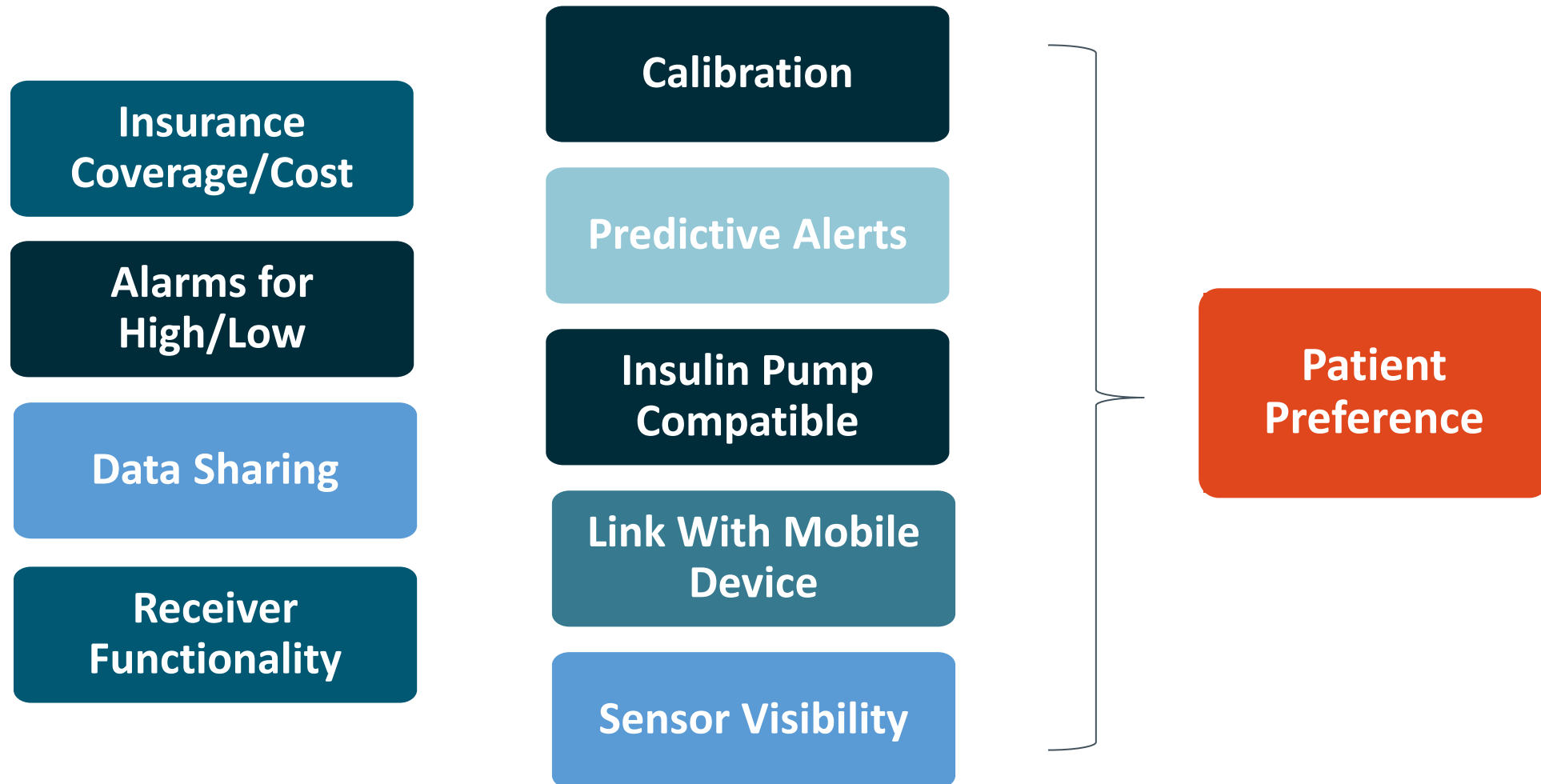


ADA – Choosing a CGM

Intermittently scanned CGMs

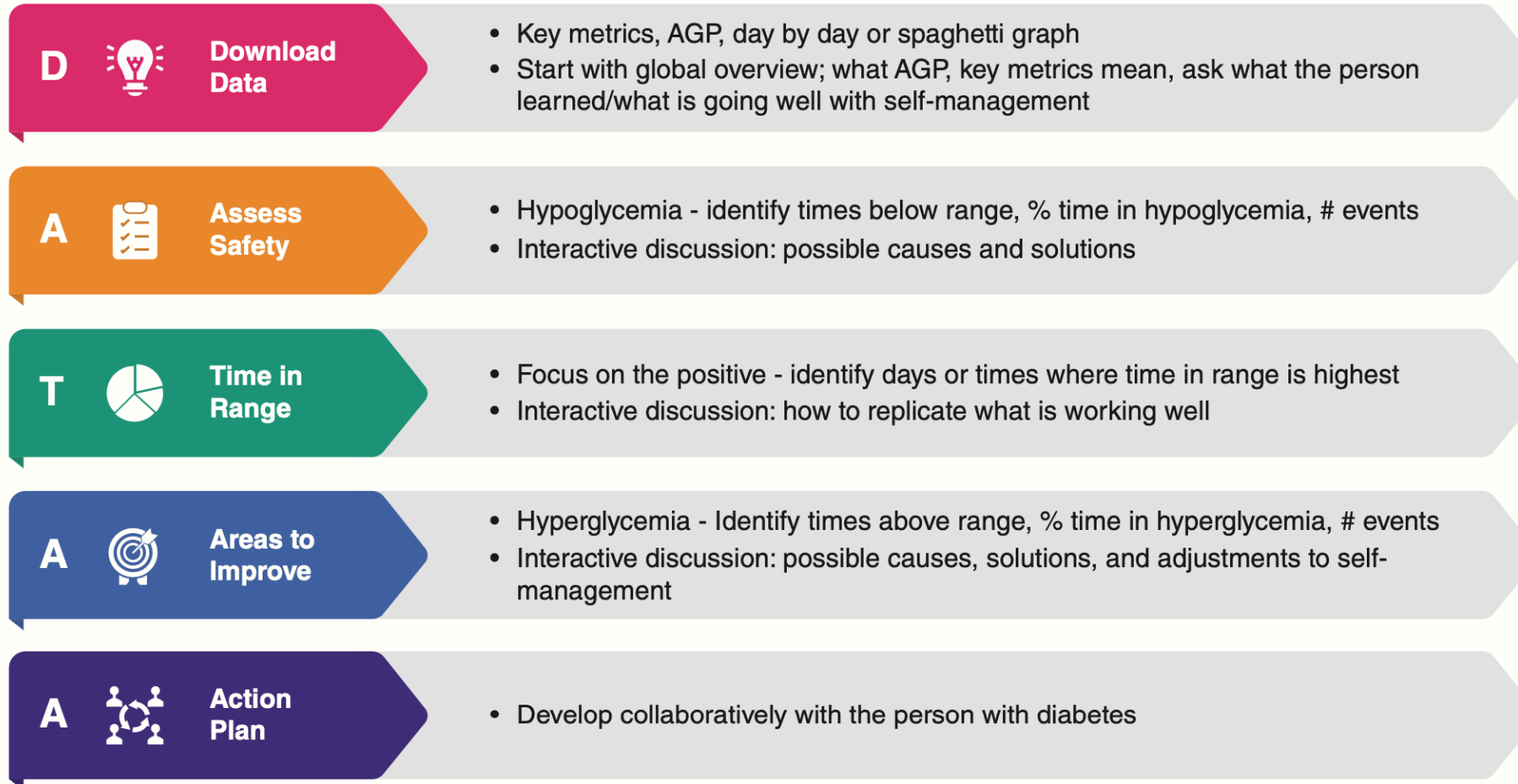
Pros	Cons
<ol style="list-style-type: none">1. Convenient and easy to use. Sensor is painless to apply, comfortable to wear, and easy to use. can scan the transmitter through clothes2. Affordable. They are much less expensive than real-time CGM devices, and they are covered by most insurance companies and Medicare.3. Shares data. Your glucose values can be shared in real time with up to 20 family, friends, caregivers, or health care providers using their smartphones.4. Eliminates finger sticks. Like the real-time CGMs, some intermittently scanned CGMs can be used to make treatment adjustments without the need for finger-stick confirmation, and some are factory calibrated, eliminating the hassle and pain of daily calibration with finger sticks.	<ol style="list-style-type: none">1. Offers no alerts.2. Requires intent. have to remember to wave the reader over the transmitter, which might not happen on days when you're busy or distracted, or at night. And there's a price for forgetting3. One version takes 12 hours to warm up. When a new sensor is inserted, the device will not show any glucose data for the first 12 hours. During this time, you will need to do finger-stick checks.4. Offers no option to calibrate. You cannot recalibrate the sensor when glucose values don't match your finger-stick results. Without the ability to recalibrate the sensor, you may need to insert a new sensor before its indicated wear time has expired.

Patient Factors and Preferences Are Key in Individualizing CGM Device Selection



DATAA model for continuous glucose monitoring

Review of CGM - DATAA



*****At each step, express that this is information, not good or bad*****

Ambulatory Glucose Profile

GLUCOSE STATISTICS AND TARGETS

26 Feb 2019 - 10 Mar 2019 **13 days**
 % Time CGM is Active **99.9%**

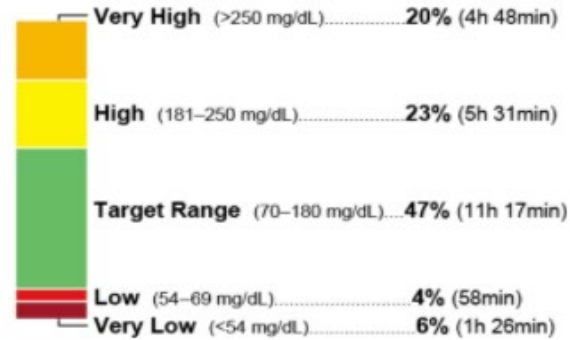
Glucose Ranges	Targets [% of Readings (Time/Day)]
Target Range 70-180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 250 mg/dL	Less than 5% (1h 12min)

Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.

Average Glucose **173 mg/dL**
 Glucose Management Indicator (GMI) **7.6%**
 Glucose Variability **49.5%**

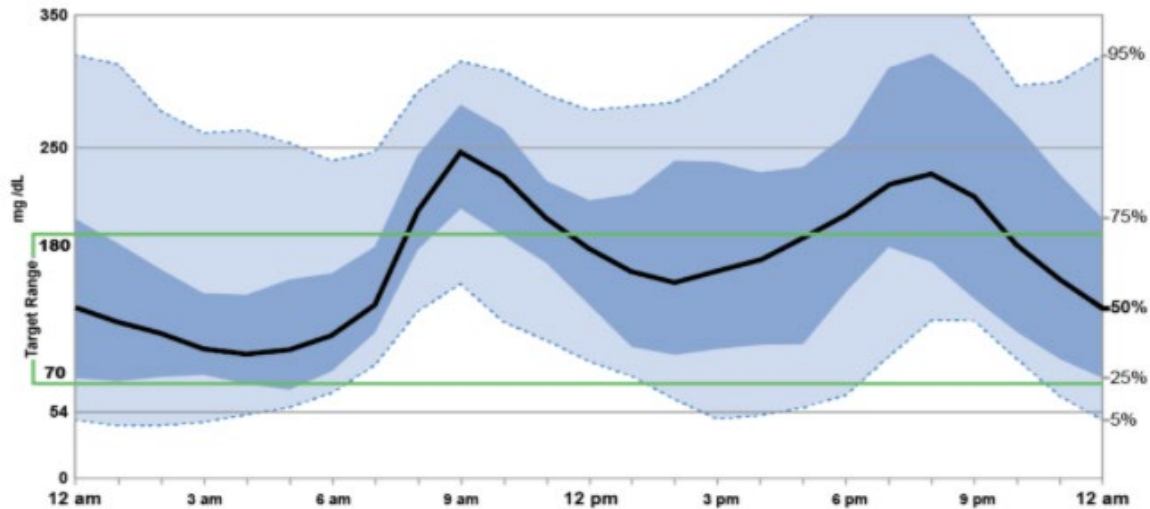
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES



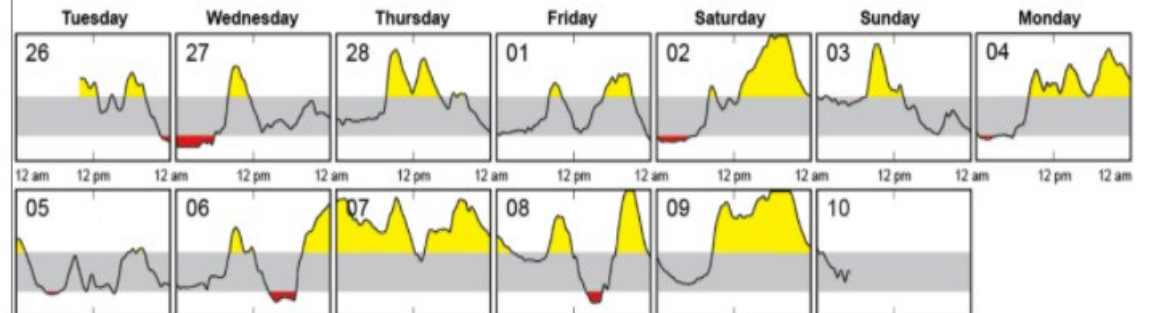
AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.



- Targets
- Statistics included
- Goals

DAILY GLUCOSE PROFILES



Each daily profile represents a midnight to midnight period.

Patents pending-HealthPartners Institute dba International Diabetes Center-All Rights Reserved. 2019

capturAGP® v4.0

Interpreting CGM Data

- The Ambulatory Glucose Profile (AGP) may be utilized to assess glycemic status in persons with diabetes.
- When using the AGP, a systematic approach to interpret CGM data is recommended:
 1. Review overall glycemic status (eg, GMI, average glucose)
 2. Check TBR, TIR, and TAR statistics, focusing on hypoglycemia (TBR) first. If the TBR statistics are above the cut-point for the clinical scenario (ie, for most with T1D >4% <70 mg/dL; >1% <54 mg/dL), the visit should focus on this issue. Otherwise, move on to the TIR and TAR statistics.
 3. Review the 24-hour glucose profile to identify the time(s) and magnitude(s) of the problem identified.
 4. Review treatment regimen and adjust as needed.



Considerations When Using CGM Data to Inform Treatment Decisions

- **Meals**

- Effects of food intake relative to insulin dose
- Can scan hourly for the first 4 hrs post meal

- **Exercise**

- BG levels before, during, immediately after, and 6 hrs after exercise

- **Illness**

- **Postinsulin dose correction**



Effective Review of AGP With Patients

Mark Directly on Profile Sheet

- Type/duration of diabetes, age, weight, insulin dose
- Usual times for waking, meals, bed
- Medication times and doses on curve
- Times for consistent exercise or snacks

Look for Patterns of Low Glucose Readings

- If 10% line touches lower target line during a particular period, action should be taken
- Immediate action is required if 25% line touches or crosses below lower target line or if 10% line reaches 54 mg/dL

Look for Patterns of High Glucose Values

- Ask if medication was forgotten or if insulin is taken before meals
- Review meal markers and patterns for weekday, weekend, or special activities
- Discuss areas of high glucose values and strategies to reduce

Agree on Action Plan

- Always treat hypoglycemia first
- When treating hyperglycemia, observe data at least 12-18 hrs past the time window for hyperglycemia; if any curves are seen in hypoglycemia range, approach conservatively

Guidance on Targets for Time in Range

Diabetes Group	Time in Range		Time Below Range		Time Above Range	
	% of Readings Time/Day	Target Range	% of Readings Time/Day	Below Target Level	% of Readings Time/Day	Above Target Level
T1D*/T2D	> 70% > 16 hr, 48 min	70-180 mg/dL 3.9-10.0 mmol/L	< 4% < 1 hr < 1% < 15 min	< 70 mg/dL < 3.9 mmol/L < 54 mg/dL < 3.0 mmol/L	< 25% < 6 hr < 5% < 1 hr, 12 min	> 180 mg/dL > 10.0 mmol/L > 250 mg/dL > 13.9 mmol/L
Older/high-risk patients† T1D/T2D	> 50% > 12 hr	70-180 mg/dL 3.9-10.0 mmol/L	< 1% < 15 min	< 70 mg/dL < 3.9 mmol/L	< 10% < 2 hr, 24 min	> 250 mg/dL > 13.9 mmol/L

Each incremental 5% increase in TIR associated with clinically significant benefits for T1D/T2D

*For age < 25 yrs, if A1C goal is 7.5%, then set TIR target to ~ 60%.

†Individualize dosing; be conservative, with strong focus on reducing percentage of time spent < 70 mg/dL (< 3.9 mmol/L) and preventing excessive hyperglycemia.



Optimizing Treatment Decisions With CGM

A1C assesses:

- **Glycemic control**
 - Does not reflect daily glycemic excursions, hypoglycemia, or PPG

CGM assesses:






- **Daily glycemic excursions**
- **Hypoglycemia**
- **PPG**
- **Time in range**
(time spent in target glucose range)
- Patient **trends** toward hypoglycemia or hyperglycemia

Trend Arrows and Bolus Insulin Adjustment














Trend Arrow	Rate and Direction of Glucose Change	Adjustment to Total Bolus Dose (Calculated Bolus + Correction)
↑	Glucose rising rapidly > 0.10 mmol/L/min (> 1.80 mg/dL/min)	Increase by 20%
↗	Glucose rising 0.06-0.10 mmol/L/min (1.08-1.80 mg/dL/min)	Increase by 10%
→	Glucose changing slowly < 0.06 mmol/L/min (< 1.08 mg/dL/min)	No change
↘	Glucose falling 0.06-0.10 mmol/L/min (1.08-1.80 mg/dL/min)	Decrease by 10%
↓	Glucose falling rapidly > 0.10 mmol/L/min (> 1.80 mg/dL/min)	Decrease by 20%

- Trend arrows indicate the rate and direction of glucose change.
- Individualized adjustments to insulin dose may be required based on patient's specific needs and profile.

Trend Arrows for Libre and Eversense

Arrow	Meaning	Change in Glucose	Correctional Factor			
			< 25	25–49	50–74	≥ 75
	Rising quickly	Increasing > 2 mg/dL/min or > 60 mg/dL in 30 min	+3.5 units	+2.5 units	+1.5 units	+1.0 units
	Rising	Increasing 1–2 mg/dL/min or 30–60 mg/dL in 30 min	+2.5 units	+1.5 units	+1.0 units	+ 0.5 units
	Changing slowly	Not increasing or decreasing > 1 mg/dL/min	No adjustment			
	Falling	Decreasing 1–2 mg/dL/min or 30–60 mg/dL in 30 min	-2.5 units	-1.5 units	-1.0 units	-0.5 units
	Falling quickly	Decreasing > 2 mg/dL/min or > 60 mg/dL in 30 min	-3.5 units	-2.5 units	-1.5 units	-1.0 units

Trend Arrows for Dexcom G6 and Medtronic Guardian

Dexcom	Medtronic	Meaning	Change in Glucose	Correctional Factor			
				< 25	25–49	50–74	≥ 75
		Rapidly Rising	> 3 mg/dL each 1 min > 45 mg/dL in 15 min	+ 4.5 units	+3.5 units	+2.5 units	+1.5 units
		Rising	Increasing 2–3 mg/dL each 1 min Up to 45 mg/dL in 15 min	+3.5 units	+2.5 units	+1.5 units	+1.0 units
		Slowly Rising	Increasing 1–2 mg/dL each 1 min Up to 30 mg/dL in 15 min	+2.5 units	+1.5 units	+1.0 units	+ 0.5 units
	None	Steady	< 1 mg/dL each 1 min Up to 15 mg/dL in 15 min	No adjustment			
		Slowly Falling	Decreasing 1–2 mg/dL each 1 min Up to 30 mg/dL in 15 min	–2.5 units	–1.5 units	–1.0 units	–0.5 units
		Falling	Decreasing 2–3 mg/dL each 1 min Up to 45 mg/dL in 15 min	–3.5 units	–2.5 units	–1.5 units	–1.0 units
		Rapidly Falling	> 3 mg/dL each 1 min > 45 mg/dL in 15 min	–4.5 units	–3.5 units	–2.5 units	–1.5 units

CGM Safety Consideration

- Clinicians should make a reasonable effort to ascertain that a person with diabetes is not inadvertently ingesting a substance or medication that will cause the CGM to deliver false or misleading information.
- Clinicians should make a reasonable effort to make persons with diabetes aware of the theoretical risk of radiation exposure to diabetes technologies.
- Persons with diabetes who have a care provider, such as a spouse, adult child of a geriatric person with diabetes, or parent of a child with diabetes, who remotely monitors glucose data, should be cautioned that remote glucose monitoring is dependent upon server functionality and that data interruption can result.
- Back-up plans of having persons with diabetes revert to SMBG or methods to communicate CGM data to those who remotely follow will be needed until functionality can be restored.

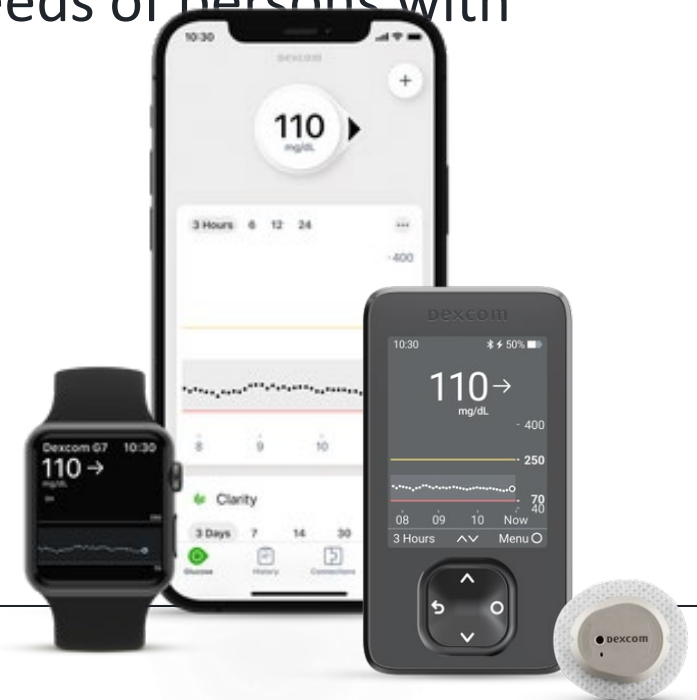


CGM Education

Who	<ul style="list-style-type: none">• Providers• Pharmacists• Patients• Nurses
What	<ul style="list-style-type: none">• Diabetes self-management education and support program specialists should assess knowledge base, review data with the person with diabetes• Individualized feedback for initiating therapy, adjustments, and/or behavioral modifications as needed to support the attainment of individualized glycemic goals.
How	<ul style="list-style-type: none">• Utilize a structured, comprehensive training program that covers all aspects of safe and effective use of diabetes technologies.
When	<ul style="list-style-type: none">• Routine education is most effective; should start several weeks-to-months before implementation

Implementation of CGM

- Initiation and use of diabetes technology should be implemented by health care professionals who are trained, committed, and experienced to prescribe and direct the use of these tools.
- Clinicians should have the infrastructure to support the needs of persons with diabetes using the technology.



Polling Question #5

▪ **Please select your top three barriers to increasing the adoption of CGMs at your organization?**

- Physician knowledge and comfort to switching.
- Patient/parent preference or comfort for CGMs.
- Confusion as to which product should be administered (Nursing).
- Cost/copay of CGM
- Variance in payer preference.



Common Barriers to Using CGM in Practice

Patient Barriers

- Cost or insurance coverage
- Aversion to wearing a device on body; wants to be detached
- Does not want to signal to others the presence of diabetes
- Denial of disease
- Overwhelmed by too much information or diabetes distress

Clinician or Clinic Barriers

- Concern regarding device operation and program implementation
 - Device ordering, set-up, download
- Lack of experience interpreting the data
- Limited time to review data or address patient concerns in clinic settings
- Concern over technology or data security
- Concern regarding workflow set-up and related costs

Limitations of CGM

- During rapid states of change, SG and BG may differ more than 20%
- The CGM needs calibrations a minimum of twice a day (once every 12 hours)
- Interference with glucose readings by sensor can occur with certain substances
 - i.e. glutathione, ascorbic acid, uric acid, salicylates
- Lag-time for up to 15 minutes when glucose c
- MARD = mean average reading deviations
 - Overall percentage of error —near 15%
 - Guardian REAL-Time -12%
 - DexCom - 9 %
 - Navigator 12-14%

Sensor Glucose (SG) vs. Blood Glucose (BG)



CGM Resources for Clinicians

AACE	https://pro.aace.com/cgm/toolkit/cgm-device-comparison https://marlin-prod.literatumonline.com/pb-assets/Health%20Advance/journals/eprac/EPRAC180.pdf
ADA	https://diabetes.org/about-diabetes/devices-technology/choosing-cgm https://diabetesjournals.org/care/article/46/Supplement_1/S111/148041/7-Diabetes-Technology-Standards-of-Care-in
Freestyle	https://www.freestyle.abbott/us-en/compare-cgms.html?dclid=CJHQ5-uVzogDFfqkpgQdcokv7Q https://www.freestyle.abbott/us-en/how-to-set-up.html?dclid=CJHQ5-uVzogDFfqkpgQdcokv7Q https://www.freestyle.abbott/us-en/myfreestyle-freestyle-libre-3.html?dclid=CJHQ5-uVzogDFfqkpgQdcokv7Q https://www.freestyle.abbott/us-en/products/freestyle-libre-3.html?dclid=CJHQ5-uVzogDFfqkpgQdcokv7Q https://www.freestyle.abbott/us-en/cost.html?dclid=CJHQ5-uVzogDFfqkpgQdcokv7Q https://www.freestyleprovider.abbott/us-en/freestyle-libre-3.html
Dexcom	https://provider.dexcom.com/products/g6-personal-cgm https://provider.dexcom.com/g7-personal-cgm https://www.stelo.com
Eversense	https://provider.eversensecgm.com/eversense-e3/
Guardian	https://www.medtronic.com/us-en/healthcare-professionals/products/diabetes/continuous-glucose-monitoring-systems/guardian-connect.html
Professional	https://www.freestyle.abbott/us-en/home.html https://provider.dexcom.com/products/dexcom-g6-pro
Others	Association of Diabetes Care and Education Specialists, APhA. Personal CGM Implementation Playbook . 2020; American Association of Nurse Practitioners (AANP). Personal CGM Implementation Playbook . 2024.

Practice Points

1. Pharmacists can be integral in helping patients with diabetes to select the most optimal technology and educating them on use of technologies as well as interpretation of data to optimize the treatment plan.
2. CGM offers significant advantages to BGM (blood glucose monitoring) with a glucose meter, including trend arrows, alerts for low and high glucose events, and metrics such as TIR (time in range) and GV (Glucose variability).
3. Consider patient-specific factors when selecting a diabetes technology and use the Identify, Configure, Collaborate Framework.
4. Data from diabetes technologies can be interpreted to adjust diabetes therapies, address lifestyle modifications, and troubleshoot management issues.
5. The DATAA (download data, access safety, time in range, areas to improve, action plan) model is a tool to interpret diabetes technology through interactive discussions. It is important to note to the patients that the numbers are only considered data and should not be labeled as good or bad.
6. Encourage patients to maximize the wear time of CGM to ensure maximum benefits.



Summary

- Overcoming barriers to CGM implementation may support use and adherence
 - Patient barriers include access issues, personal comfort/acceptance, diabetes distress
 - Clinician or clinic barriers include operational logistics, lack of experience, time constraints, technology concerns, etc
- Novel parameters for personalized glucose control need to be interpreted and used adequately
 - Time in range, glucose profile, AGP, trends

Thank You



Assessment Question #1

M.L., a 70-year-old woman with type 2 diabetes mellitus (T2DM), is on insulin glargine 35 units at night and insulin aspart before meals. She has an insulin/carbohydrate ratio (ICR) of 1:10 and a correction factor of 1:40 for glucose over 150 mg/dL. M.L.'s medical history also includes hyperlipidemia, hypertension, and osteoarthritis. Her home drugs include lisinopril 10 mg daily, atorvastatin 40 mg daily, aspirin 81 mg daily, acetaminophen 1 g three times daily as needed, cholecalciferol 1000 units daily, ascorbic acid 1000 mg daily, and a multivitamin. Her most recent A1C is 9.3%. M.L. reports waking up with blood glucose readings in the range of 60–70 mg/dL three times a week but has no symptoms. M.L. monitors her fingersticks two or three times per day. She owns a smart phone.

Because her sister uses a continuous glucose monitor (CGM), M.L. wonders if she could also get one for glucose monitoring. Which one of the following would best justify insurance coverage of a CGM in M.L.?

- A. Checking two or three times per day
- B. A1C not at goal of <7%
- C. Hypoglycemia unawareness
- D. Therapy with multiple daily injections (MDI)

Assessment Question #2

M.L.'s insurance covers the Freestyle Libre 2 CGM or the Freestyle Libre 14-day CGM. She asks what the differences are between the features to help her select which might be best. Which one of the following CGMs is best to recommend for M.L.?

- A. Freestyle Libre 2, because it has audible alarms for her morning lows
- B. Freestyle Libre 2, because it has improved accuracy over the 14 day Libre
- C. Freestyle Libre 14 day, because she has a smart phone
- D. Freestyle Libre 14 day, because it has a longer sensor wear time

Assessment Question #3

M.L. begins to use CGM. Before lunch she scans her sensor and sees a glucose value of 379 mg/dL, having no hyperglycemia symptoms, she checks a fingerstick which shows a glucose level of 188 mg/dL. Which one of the following is the most likely cause of M.L.'s falsely elevated sensor reading?

- A. Acetaminophen interaction
- B. Ascorbic acid dose greater than 500 mg/day
- C. Lag time
- D. Missing her pre-breakfast aspart dose

Assessment Question #4

M.L. is going to eat her lunch which contains 50 g of carbohydrates. She scans her sensor to obtain her pre-lunch glucose value. She gets 210 mg/dL with the directional arrow horizontal. Which one of the following is best to recommend for M.L.'s insulin aspart dose?

- A. 6 units
- B. 8 units
- C. 9 units
- D. 10 units

Assessment Question #5

Which one of the following patients is most likely to benefit from a professional CGM?

- A. 70-year-old with T2DM on metformin monotherapy not monitoring blood glucose with A1C of 7.3%
- B. 46-year-old with T2DM and A1C of 9.6% with fasting blood glucose averaging 115–135 mg/dL
- C. 32-year-old woman with gestational diabetes mellitus not on medications and A1C of 6.6%
- D. 16-year-old with type 1 diabetes mellitus (T1DM) and A1C of 6.8% checking fingersticks 4 to 6 times per day

Assessment Question #6

K.J. at 17-year-old male with T1DM is looking for recommendations on products to cover CGM sensor for when he has long swim practices or meets to prevent it from falling off. Which one of the following types of products is best to recommend for K.J.?

- A. Skin-Tac
- B. Simparch
- C. CGM sensors should never be covered
- D. Medical tape

Assessment Question #7

K.J. has a follow-up video visit after his initial sensor wear. The remote data is reviewed from his CGM over 14 days, with the following values: 10% time greater than 250 mg/dL; 36% time greater than 180 mg/dL; 60% time in range (TIR) 70–180 mg/dL; 3% time less than 70 mg/dL; 0% time less than 54 mg/dL; 8.3% glucose management indicator; 35% glucose variability (GV), 71% sensor wear; and 184 mg/dL average glucose. Which one of the following parameters best matches the targets for K.J.?

- A. TIR, sensor wear, time below range (TBR)
- B. TIR, time above range (TAR), TBR
- C. Sensor wear, GV, time above 250 mg/dL
- D. TBR, GV, sensor wear

Assessment Question #8

A 54-year-old man with T1DM recently started the T:Slim hybrid closed-loop system. Upon reviewing his data, it is noted he is only in automated mode 60% of the time. Which one of the following would be the best counseling point to help this patient stay in automated mode?

- A. Continuously wear the CGM sensor.
- B. Change the infusion every 3 days.
- C. Eat a low carbohydrate diet
- D. Use temporary basal rates.

Assessment Question #9

A 50-year-old woman takes glimepiride 8 mg daily and metformin 1000 mg twice daily. Her A1C is 8.2%. She reports overnight sweats and fatigue. Which one of the following would best determine whether this patient's symptoms may be related to hypoglycemia?

- A. Professional CGM
- B. Personal CGM
- C. Hybrid closed-loop insulin pump
- D. Connected pen