CGM AND OTHER DIABETES TECHNOLOGY BRIANNA PATACINI, PHARMD, BCACP, CDCES, MBA JAMES HUANG, PHARMD, BCACP, CDCES

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OBJECTIVES

- Select an appropriate patient for continuous glucose monitoring
- Identify elements of continuous glucose monitor reports and interpret data for clinical use
- Recognize available diabetes technology options including integrated systems

Illustrate possible solutions to common CGM issues such as sensor adhesion, skin irritation, and accuracy
concerns

CONTINUOUS GLUCOSE MONITORING

THE BASICS

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NOTABLE ABBREVIATIONS AND DEFINITIONS

SMBG: Self-monitoring of blood glucose

CGM: Continuous glucose monitor

rtCGM: Real-time CGM -- Systems that measure and display glucose levels continuously.

isCGM: Intermittently scanned CGM -- Systems that measure glucose levels continuously but only display glucose levels when swiped by a reader or a smart device.

Personal CGM: Owned by the person with diabetes and used to make management decisions.

n Diabetes Association, 7. Diabetes Technology: Standards of Medical Care in Diabetes – 2021. Diabetes Care. 2021;44(suppl 1):585-599. Continuous Glucose Monitoring Implementation Playbook. <u>https://www.diabetgeeducato.org/practice/practice-tookiapa-resource</u>aloref

Professional CGM: Owned by the clinic and worn by the person with diabetes (generally 7-14 days). Data may be blinded or visible to the person wearing the device.























KEY FEATURE	s of personal c	CGM DEVICES	
	Abbott Freestyle Libre 14 day	Abbott Freestyle Libre 2	Dexcom G6
Approved Age (years)	≥18	≥4	≥2
Calibrations	None	None	None (can calibrate as needed)
Approved Site	Arm	Arm	Abdomen*
Sensor wear (days)	14	14	10
Available frequency of glucose measurement	Every Minute	Every Minute	Every 5 minutes
Real time Alarms/Alerts	No	Yes	Yes
Insulin pump integration	No	Not yet available	Yes (Tandem t:slim X2)
Software compatibility	Reader, Apple and Android Smartphones	Reader, Apple Smart phones, Android soon	Receiver, Apple and Android smartphones, Smartwatches
Interfering substances	Vitamin C, Salicylic Acid	Viramin C	Hydroxyurea



AMBULATORY GLUCOSE PROFILE INTERPRETATION











REVIEWING DATA		
	-	
Description	Most TIDM/T2DM	Older/High Risk TIDM/T2DM
	14 days	14 days
	70% of data from 14 days	70% of data from 14 day
	Individualized	Individualized
Estimate of current HbA1c level	Individualized	Individualized
Measurement of glycemic variability	≤36%	≤36%
% and time > 250 mg/dL	<5%	<10%
% and time 181 - 250 mg/dL	<25%	
% and time 70 - 180 mg/dL	>70%	>50%
-	Description Estimate of current HbA1c level Measurement of gycemic variability % and time > 250 mg/dL % and time 181 - 250 mg/dL	Description Most T IDM/T2DM 14 days 70% of data from 14 days 16 dividualized Individualized Estimate of current HbA1c level Individualized Measurement of glycemic variability \$36% % and time > 250 mg/dL <5%







ENERAL I	NSURANCE COVERA	GE	
	Medicare	Medicaid	Commercial
Criteria	I - 3+ injections of insulin	Type I diabetes	Highly variable coverage
	daily <u>and</u>	Type 2 diabetes*	No co-pay assistance
	Checking blood sugar I time daily and		cards available
			May have a preferred
	Seen by provider every 6 months	*dependent on specific Medicaid criteria	CGM for patients with type 2 diabetes
Where	Usually DME	DME or Pharmacy	DME or Pharmacy



ORDERING PROCESS- MEDICARE/MEDICAID

- Office visit (face to face or virtual) within 100 days; notes must include the following:
- Diagnosis (TIDM or T2DM or other) Testing frequency (I + time per day)
- Insulin regimen (3+ injections/day or insulin pump)
- Patient requires frequent adjustments of the insulin treatment regimen, based on therapeutic CGM test results
 Complete Standard Written Order (SWO); DME supplier to provide this
- Fax SWO and chart notes to DME supplier
- Example phrasing: JW has type 2 diabetes and tests blood sugars 3 times per day. He is taking a combination of basal
 and prandial insulin with a total of four injections per day. He uses a sliding scale regimen for his prandial insulin (2 units
 per 50 mg/dL above 150 mg/dL) and requires frequent adjustments of the insulin treatment regimen, based on
 therapeutic CGM test results.

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SETTING PATIENT EXPECTATIONS

- Insurance approval is NOT guaranteed
- CGM approval through insurance can take 1-2 months depending on insurance (although approval can occur immediately)

BILLING FOR	CGM SERVICES	
CPT Code	Description	Who Performs
95249 Personal-use CGM startup/training	Requires documented ambulatory CGM data for a minimum of 72 hours Patient-provided equipment, sensor placement, hook-up, calibration and monitor, patient training, and printout of recording	Any trained health care professional (e.g., nurses, certified diabetes care and education specialists, pharmacists)
95250 Professional-use CGM placement	Requires documented ambulatory CGM data for a minimum of 72 hours Physician or other qualified health care professional (office)-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording	Any trained health care professional (e.g., nurses, certified diabetes care and education specialists, pharmacists)
95251 Personal- and professional-use CGM interpretation	Requires documented ambulatory CGM data for a minimum of 72 hours; analysis, interpretation, and report	A physician or licensed non-physician provider as outlined by their scope of practice in individual state practice acts

	RVICES	
	Medicare physician office fee schedule	Private Payer (2021 averages)
	ricultare physician office fee schedule	(1021 arenages)
15249 – Personal-use CGM tartup/training Sill only once during the time period that he patient owns device	\$59.87	\$128
25250 – Professional-use CGM placement Do not bill more than 1 x/month	\$151.57	\$309
25251 – Personal- and professional- use CGM interpretation Do not bill more than 1x/month	\$35.30	\$97
9212-99215 – Established patient n non facility or office setting oppopriate billing determined by office	\$57.45 - \$183.07	\$87 - \$288

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CONTINUOUS GLUCOSE MONITORING

PATIENT CONSIDERATIONS

PATIENTS MOST LIKELY TO BENEFIT FROM CGM

- Type I Diabetes
- Type 2 diabetes with at least 1 of the following:
- On an intensive insulin regimen (multiple daily injections or insulin pump)
- History of severe hypoglycemia or hypoglycemia unawareness High degree of glycemic variability/Unclear glycemic pattern
- Difficulty achieving individualized glycemic goals
- Discordant AI c and SMBG
- Need for monitoring of recent glycemic changes (lifestyle change, pre-surgery, etc)

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OTHER PATIENT CONSIDERATIONS

- Need for alerts for high/low glucose
- Cost/Coverage
- Ability/Desire to use technology
- Ability to share glycemic data with provider (computer, smartphone, or ability to come to clinic)
- Integrated Technology (insulin pumps, smart insulin pens, other diabetes technology, smartphone, smartwatch)
- Ability to reliably scan intermittent CGM if this is chosen
- Tolerability of Sensor and Adhesive
- Choice between personal use CGM and professional CGM

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CONTINUOUS GLUCOSE MONITORING TROUBLESHOOTING

ADHESION

Make sure that the site is clean and free of any lotions, creams, or oils prior to placing sensor

- Over-the-top adhesives (e.g. Tegaderm[™])
 Place over or around the sensor or infusion set after insertion and reapply as needed.
- Liquid Adhesive (e.g. Skin-Tac™)
 Place on the skin prior to the sensor or infusion set to help it stick.
 Make sure these are completely dry on the skin before placing site
- Non-adhesive options (e.g. Ace[™] or Coban[™])
 If unable to tolerate adhesive products or to protect the site if needed.
 Make sure to way loosely and generally for short term use only; remove at night to avoid compression

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SITE IRRITATION

- Important to clarify if irritation is occurring during sensor wear or after removal to determine if possibly related to reaction to
 adhesive versus a result of skin stripping with removal
- Steroid nasal spray (e.g. fluticasone)pr of her steroid applied to topically
 Starp over outristikant all advances to proprosteket by door placing new endoror infusion set.
 Crasms and ointments can be used for irritation after removing the adhesive but will likely make it harder for the device to stay in place if used
 under sensor
- Barriers/Tapes/Hydrocolloid pad (e.g. Tegaderm[™])
 Place barrier first, then sensor over the top so that the adhesive is not in direct contact with the skin
- Adhesive remover (e.g. mineral oil or Tac Away [®] wipes)
 Removes adhesive, reduces intration and skin stripping
 Use to help remove sensor and adhesive then wipe skin to remove any remaining residue

- Barrier wipes (e.g. Smith and Nephew™ IV Prep)
 Use to prevent irritation, adhesive buildup, friction, or abrasion
 Wipe site and allow to dry completely before placing the sensor
- Oral antihistamine
 May take consistently or as needed for symptoms

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CGM ACCURACY

- Mean Absolute Relative Difference (MARD)
- ≤10% is appropriate for insulin dosing Most current systems have MARD 8-10%
- Sensor readings lag ~5-10 minutes behind which can be meaningful, particularly in times of rapid glucose change
- Calibration may worsen accuracy if done incorrectly
- Calibration (if required by the system or if needed due to sensor inaccuracy) is an input of a fingerstick blood glucose Calibration can be done when glucose stable and reading is consistently high or consistently low
- Sensor placement can matter
- MARD is at the approved sensor sites
- Other sites have been studied or used by patients off-label but encourage monitoring for accuracy in these situations

- One study with alternate sites for Libre 14 day found similar accuracy on the upper thigh but worsened accuracy on the abdomen
- Accuracy varies by day of sensor wear with first day often having more accuracy concerns

CGM ACCURACY

- Interfering Substances Dexcom G6[™]
 - Hydroxyurea causes false elevations
 - Acetaminophen >1000 mg q6h may falsely elevate sensor readings

- Freestyle Libre[™]
- Vitamin C: >500 mg/day may falsely elevate sensor reading
 Aspirin:>650 mg may falsely lower sensor reading Libre 14 day
 Medtronic Guardian[™]
- Acetaminophen may falsely elevate sensor reading
 Hydroxyurea may falsely elevate sensor reading
- Eversense[®]
- Tetracycline may falsely lower sensor reading
 Mannitol may falsely elevate sensor reading

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CGM ACCURACY

Main points for patients:

If sensor reading does not match symptoms, then double check with fingerstick!

- * Do NOT calibrate the sensor when glucose is rapidly changing
- If significantly inaccurate call the manufacturer
- If the sensor requires calibration make sure to calibrate as directed Accuracy may be affected by sensor site placement if using off-label

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INTEGRATED DIABETES TECHNOLOGY

SMART INSULIN PENS

General Components

- Insulin delivery with pens or cartridges
- CGM connection
- Smartphone app
- Patient Considerations
- Patient with need/want for insulin dose tracking or dose calculation assistance

- Reduce risk of insulin stacking
 Reduce risk of accidental duplicate or missed doses
- Improve adherence to more complex dosing regimen

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INPEN [™]	
<i>a</i>	Laplack Lopics
Smart insulin pen paired with InPen [™] app	Today January 11, 2020 Average Total Total
Tracks insulin doses and active insulin	Skole Insulin Carbo 145 mg/d, 12.5 v 60 g
Can assist with dose calculation for mealtime insulin	1 1 1 1
 Works with Novolog[®], Fiasp[®], or Humalog[®] cartridges but functions like a typical insulin pen in delivering insulin 	~
Can include reminders and alerts in the app	All Agentacing
 Able to pair with CGM (Dexcom or Medtronic Guardian "Connect) and generate reports for personal or healthcare team review 	Dansen Transis Dansen Transis
	Die Australie Contraction Contraction
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INSULIN PUMPS

General Categories

- Non-integrated pumps: No direct connection between pump and CGM though can be used simultaneously
- Patch pumps: Tubeless insulin delivery systems
- Sensor-augmented pumps: Use a pump and a CGM together but utilizes user settings and inputs only for insulin delivery

- Sensor-integrated pumps: Use a pump and CGM together with algorithm to adjust pump based on CGM data
- Low glucose suspend/predictive low glucose suspend
 Automated insulin delivery: Hybrid closed loop





INSULIN PUMPS

- Patient Considerations
- Affordability/coverage
- Insulin requirements/Pump reservoir limits
 Ability to safely manage device
- Jointy to sately manage dence
 Intensive insulin regimen with frequent glucose monitoring
- Most insulin pumps deliver basal and bolus with rapid acting insulin
- Calculating insulin quantity needed: total daily dose + amount needed for tube filling/waste
- Most insulin pumps use carb ratio and correction factor/insulin sensitivity factor for dose calculation

Not all rapid acting insulins are approved for use in every pump

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QUESTION #1

Which of the following is a benefit of continuous glucose monitoring?

a. Improvement in A1c

- b. Decrease in hypoglycemia in patients with type 1 diabetes with tight glycemic control
- c. Improvement in diabetes distress and patient satisfaction

d. All of the above

year old male with recent A1c 7.1%; which is the best
High to cheve His in the
Target Range Incompt. SITs commun.
Les is man Di son
Very Law of Law Distance
Low is man. 1% room

QUESTION #3

A patient with Type 1 diabetes is currently using a Dexcom[™] G6 CGM with an insulin regimen of Lantus 16 units nightly and Novolog before meals based on a carb ratio of 1:15 and correction of 1:50. He would like to know about technology options that may help him with calculating his bolus does as reducing risk of hypoglycemia from stacking insulin. Which of the following technology options would be best to consider? a. InPen[™] b. Bicfort Unitw[™] curtern

b. Bigfoot Unity[™] system
c. Novopen Echo[®]

d. Eversense®

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QUESTION #4

A patient has been using their CGM for the past 6 months. They are diligent about rotating and cleaning the sensor site, but are having issues with the sensor adhesive loosening after the first 72 hours. Which of the following options is most appropriate for the patient?

a. Apply fluticasone nasal spray over the entire sensor site before applying the sensor

- b. Place a liquid adhesive on the skin prior to sensor application
- c. Use a protective film wipe topically before applying the sensor
- d. Tightly wrap an $\mathsf{Ace}^{^{\mathrm{M}}}$ wrap over the sensor when it starts to loosen









	Libre	Libre 2	Dexcom G6
MARD (Accuracy)*	9.4%	9.2%	9.0%
Ability to Share Data in Real Time Remotely/App Availability	Yes	Not available yet- FDA approval for app applied for and pending	Yes
Alarms	No	Yes- available every minute	Yes
Interfering Substances	Vitamin C, Salicylic Acid	Vitamin C	Hydroxyurea
Approved Sites for Sensors	Arm- subcutaneous	Arm- subcutaneous	Abdomen- subcutaneous
Sensor Warm Up Period	I hour	l hour	2 hours
Sensor Wear	14 days	14 days	10 days
Age Approved For	Adults ages 18 and up *MARD = mean absolute re	Adults & children age 4 and	Adults & children age 2 and up



















NDARROWS				
Reader	Glucose Direction	Change in Glucose		
1	Rising quickly	Glucose is rising quickly Increasing >2 mg/dL/min or >60 mg/dL in 30 minutes		
7	Rising	Glucose is rising Increasing 1-2 mg/dL/min or 30-60 mg/dL in 30 minutes		
->	Changing slowly	Glucose is changing slowly Not increasing/decreasing >1 mg/dL/min		
М	Falling	Glucose is falling Decreasing 1–2 mg/dL/min or 30–60 mg/dL in 30 minutes		
+	Falling quickly	Glucose is falling quickly Decreasing >2 mg/dL/min or >60 mg/dL in 30 minutes		