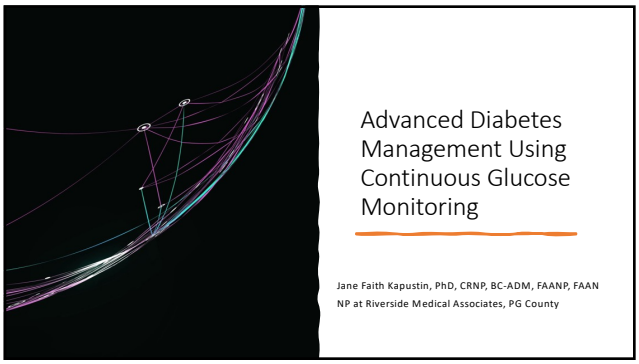


Advanced Diabetes Management Using Continuous Glucose Monitoring

Jane Faith Kapustin, PhD, CRNP, BC-ADM, FAANP, FAAN
NP at Riverside Medical Associates, PG County

1

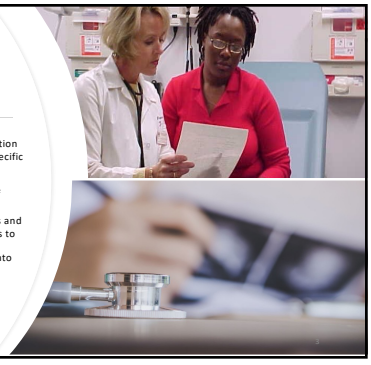
Disclosures

- ´ADVISORY BOARD, ACELLA PHARM.
- ´ADVISORY BOARD, SANOFI
- ´SPEAKER, SANOFI

2

Objectives:

1. Review the American Diabetes Association (ADA) Standards of Medical Care that are specific to CGM use in clinical practice.
2. Describe the available types of CGM in terms of features, accuracy, and the types of patients who would benefit from them.
3. Analyze CGM data by using daily graphs and the ambulatory glucose profile (AGP) reports to inform treatment recommendations.
4. Establish strategies to integrate CGM into practice to improve overall diabetes-related outcomes.



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Diabetes

- More people diagnosed with diabetes daily
  - Over 38 million have type 2
  - About 1.9 million have type 1
- NHANES data demonstrate few people meet goals of therapy for diabetes and co-morbid conditions
- Technological advances occur quickly, people can benefit from them
  - CGM represents one advance that people are demanding
  - Can greatly improve overall glycemic control and prevent risks for hypoglycemia
    - Reduces hospitalizations
    - Reduces costs
    - Reduces morbidity and mortality

1. Center for Disease Control and Prevention. Prevalence of diagnosed diabetes. Sept 2022. https://www.cdc.gov/diabetes/data/statistics-report/diagnosed-diabetes.html

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Who Benefits from CGM

Newly diagnosed
Those who do not check glucose
When glucose and a1c don't match
Suspect hypo events; insulin or SU use
Pregnancy, children with diabetes
Unstable patients, uncontrolled status
New to practice
When post-prandial excursions are suspected
Hypoglycemia unawareness

5

5

CGM Guidelines

- Covered by ADA guidelines
  - Encourages use to promote safety and optimize control for those on MDI or insulin pump
  - Level A recommendation for use with Pt with insulin injection
- AACE (American Association of Clinical Endocrinology)
  - Strongly encourages use of RT CGM for all those using intensive insulin therapy

6

6

Case: Peg, 69-year-old Female

- Type 2 for 7 years
- Meds:
  - Glimepiride 4mg daily
  - Metformin 1000 mg BID
  - Semaglutide 1 mg weekly
- A1c 9%
- Fasting glucoses 130-180 mg/dL

- Plan to start glargine 12 units daily
- Pt willing to try a professional CGM trial run

7

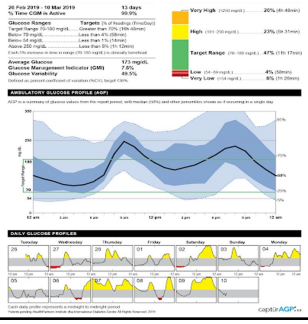
7

Peg's AGP

13 days recorded

TIR 47%
- 180 23%
- > 250 20%
- < 70 10%

- Average = 173
- GMI= 7.6%
- CV 49%



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Peg

Detected some surprises

She is interested in continuing CGM

What device would you recommend for her?
Will her insurance cover it?
What will her cost be?

She is concerned about accuracy and costs…

What can you tell her about devices?

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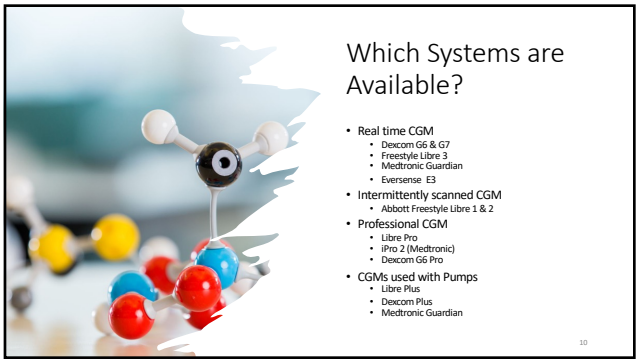

Which Systems are Available?

- Real time CGM
  - Dexcom G6 & G7
  - Freestyle Libre 3
  - Medtronic Guardian
  - Eversense E3
- Intermittently scanned CGM
  - Abbott Freestyle Libre 1 & 2
- Professional CGM
  - Libre Pro
  - iPro 2 (Medtronic)
  - Dexcom G6 Pro
- CGMs used with Pumps
  - Libre Plus
  - Dexcom Plus
  - Medtronic Guardian

10

10

Use of CGM

- Gives patients immediate feedback
- Helps them engage in 'dietary monitoring'
- Provides data that can offer less glucose variability, helps mitigate hypoglycemia

11

11

What is the most influential factor for success with CGM?

- Overall, CGM beneficial outcomes are many:
  - Improved a1c
  - Improved TIR
  - Less hypoglycemia
  - Reduced hospitalizations
  - Reduced work or school absenteeism
- Most influential factor overall?
  - Pt engagement with CGM
  - Most likely to demonstrate change in behavior based on the data (better food choices, more exercise)

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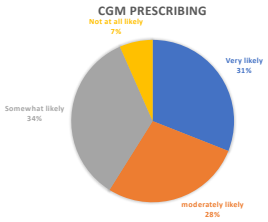
Barriers to CGM USE: Study of 602 HCPs regarding CGM prescribing



Oser TK, Hall TL, Dickinson LM, et al. Continuous glucose monitoring in primary care: Understanding and supporting clinicians' use to enhance diabetes care. Ann Fam Med. 2022;20(6):541-547. doi:10.1370/afm.2878

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13

Use of Professional CGM (owned by clinic)

- Code 95250
- Placed on pt, use either blinded or unblinded version
- Must document:
  - Insertion site, Pt education about its use
  - Professional transmitter ID number and expiration date
  - Date sensor removed
  - Print out of data (must have 72 hours of data to code and bill for it)
- HCP can interpret data on return visit (can bill once per month)
  - Use code 95251 for CGM interpretation
  - Can be billed with virtual visit
  - Must be MD, NP, PA, or CNS to bill for it
  - Pharm D can interpret but it is billed under HCP

14

14

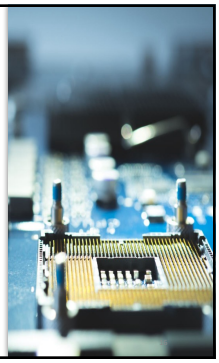
CPT Code	Services	Who Can Perform Services	Reimbursement
95249	**For personal CGM**: Ambulatory CGM >72 hours; equipment provided, sensor placement, hookup, calibration of monitor, PWD training, and printout of recording	RN/LPN, PharmD/RPh, RD, CDCES, MA, Physician, NP, PA: billed by the supervising physician, advanced practitioner or hospital outpatient department	Medicare: $61.67 Private: $130
95250	**For professional CGM**: Ambulatory CGM >72 hours; equipment provided, sensor placement, hookup, calibration of monitor, PWD training, removal of sensor, and printout of recording	RN/LPN, PharmD/RPh, RD, CDE, MA, Physician, NP, PA: billed by the supervising physician, advanced practitioner or hospital outpatient department	Medicare: $147.07 Private: $320
95251	**For personal or professional CGM**: Ambulatory CGM >72 hours; analysis, interpretation and report	Physician, NP, PA Pharmacists can do this in many states with a collaborative practice agreement	Medicare: $34.56 Private: $98

15

15

Personal CGM

- Code 95249 for start up in clinic first time
  - Can only be used one time for that CGM device
- Can still use 95251 for interpretation of data
  - Need at least 72 hours of data
  - Documentation is same
- Pt teaching—where to place sensor, how to use with insulin pump, instructions about arrows with device, use in shower/bath, use of transmitter (Dexcom only)
- Where patient can obtain sensors, readers
  - Pharmacy
  - DME (Medicare), mail order
- Both devices have intro kits (Hello Dexcom, Libre packet with scannable instructions)



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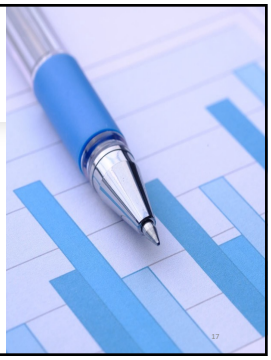
Data Interpretation

- Look at AGP
- Discuss results with patient
  - Focus on TIR
  - Focus on hypo events
  - Glycemic variability (Coefficient of Variation) < 36% considered stable
  - Look at day-to-day graphs
- Clinical decision-making
  - Document how it guides the treatment plan
- Remember—Medicare will examine notes every 6 months along with medical necessity document



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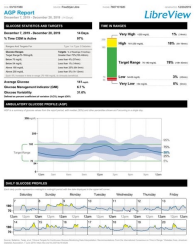
17

CGM Data Interpretation

- AGP is generated --Ambulatory Glucose Profile (Libre in example)
- Standardized one page summary of CGM metrics
  - Percent of time using CGM
  - TIR
  - Percent of time > 180, 240
  - Percent of time < 70
  - CV
  - Average
  - GMI



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- Generated at: Fri, Mar 15, 2024 10:57 AM EDT
- Reporting period: Sat Mar 2, 2024 - Fri Mar 15, 2024
- ----------
- Glucose Details
- Average glucose: 179 mg/dL
- Standard deviation: 79 mg/dL
- GMI: 7.4%
- ----------
- Time in Range
- Very High: 18%
- High: 23%
- In Range: 57%
- Low: 1%
- Very Low: <1%
-
- Target Range
- 70-180 mg/dL
-
- ----------
- CGM Details 7.8%
- Sensor usage: 93%
- Days with CGM data: 13/14
-

Cut and paste from actual Patient, Dexcom Clarity app

19

This is my chart entry

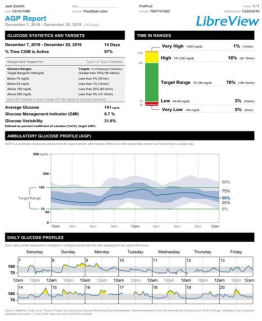
- Type 1 on basal bolus therapy, too much glucose variability, too many lows
- Is taking basal bolus insulin, toujeo 30 units daily, adjusts Humalog TID AC
- Does not use ICR but does try to count carbs
- Uses cecur for bolus but feels it acts too slowly
- would benefit from small dose GLP for control PP levels
- See dietitian. Keep food diary for dietitian to see. Needs more carb counting education, ICR rates per meal
- HLD at goal
- mild anemia--will discuss with hematology
- If insurance will not cover GLP, will give pt low dose ozempic samples to keep her TIR better. (can pick up sample in office)

20

AGP

- In this example:

- 14-day report
- 97% use of active CGM
- TIR 78%
- > 180 18%, > 240 1%
- < 70 3%, very low 0
- Average 141
- GMI 6.7%
- CV 31.6%



21

DATAA Process

- Download data—key metrics
- Assess safety—hypo events
- Time in Range—focus on positives
- Areas of improvement—identify causes of lows, highs
- Action Plan—collaboratively developed with pt

22

22

Features of CGM


Trend graphs


Customizable high/low alerts


Trend arrows indicate rate of change for last 15 minutes


Data may be shareable


Can download data for analysis

23

23

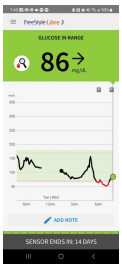
Trend Arrows

FreeStyle Libre System Trend Arrows		
Reader	**Glucose Direction**	**Change in Glucose**
↑	Rising quickly	**Glucose is rising quickly** Increasing >2 mg/dL/min or >60 mg/dL in 30 minutes
↗	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
↘	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
No arrow present indicates that the system cannot calculate the velocity and direction of the glucose change.		

24

24

Note the trend arrows and droplet here



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Sensor Placement

- FDA approved sites
  - Back of arm
  - Abdomen
  - Outer thigh
  - Upper buttocks

26

26

Case: Christine, 77-year-old female, widow, lives alone

- Has had type 2 diabetes for over 20 years. Medical history
  - HTN
    neuropathy
  - HLD
    Retinopathy OU
- Medications
  - Xigduo 5/1000mg, takes 2 daily
  - Basal insulin 32 units daily
  - Valsartan 80 mg daily
  - Rosuvastatin 20 mg daily
  - Gabapentin 300 mg BID
- Last a1c 7.2%
- Rarely checks glucose levels at home. Today glucose 162 in office (fasting)

27

27

Christine

- She asks about the "button thing" to wear on her arm so she does not have to stick her fingers
- Reports she often wakes up in the middle of the night from bad dreams and diaphoresis, 2-3 times per week
- Does she qualify for CGM?

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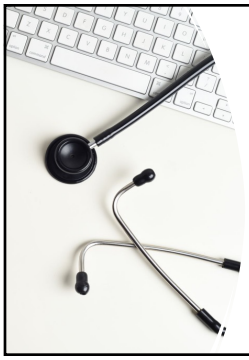

Medicare Requirements for CGM

- Medicare Eligibility Requirements for Personal CGM
  - Diagnosis of diabetes
  - Beneficiary (or beneficiary's caregiver) has sufficient training using the CGM prescribed
  - The CGM is prescribed in accordance with its FDA indications for use

29

29

CGM Medicare Rules

- Currently, to qualify for CGM therapy, a Medicare beneficiary:
  - 1. Have diagnosis of diabetes
  - 2. administer at least one dose of insulin daily or use an insulin pump
  - OR
  - experience problematic hypoglycemia*
  - 3. patients must meet with their treating practitioner every six months
- CGM is obtained by Medicare approved DME company
- Medicare audits documentation every 6 months and requires copies of notes with very specific information included

- (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or,
- A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

30

30

Partner with our direct DME suppliers for your medicare fee for service patients

Advanced Diabetes Supply	866-976-9110	J&B Medical Supply	800-737-0045
Better Living Now	800-854-5729	Mini Pharmacy	888-545-6464
Bridgewater Health Supplies	800-974-2055	Quest Health Solutions	877-888-7050
Byram Healthcare/Apria	800-775-4372	Solara Medical Supplies/AdaptHealth	844-381-8032
CCS Medical	800-599-7521	Total Medical Supply	877-670-1120
Diabetes Management & Supplies/AdaptHealth	888-738-7929	United States Medical Supply	877-270-6508
Edgepark Medical Supplies	844-619-4650	US HealthLink	855-421-2732
Edwards Health Care Services	800-951-1725		

Last Updated 3/2023

31

31

Chart notes

Document

CGM AGP with your interpretation of it
times checking glucose
Number insulin injections (basal + bolus) or on insulin pump
Adjusting insulin based on CGM reading interpretation

Need to provide this every 6 months now

Now requiring attendance at DM class, compliance with therapy

32

32

Christine: qualifies for CGM?

MEDICARE AGE

ON BASAL INSULIN

MOST LIKELY HAVING NOCTURNAL HYPOGLYCEMIA

33

33

How to Choose the Device

- Based on many factors:
  - personal or professional use
  - blinded or unblinded
  - continuous versus intermittently scanned (flash)
  - 14 days or 10 days for sensor life
  - high and low alarms
  - Need insulin pump closed-loop interconnectivity
  - implantable or cutaneous placement
  - Make sure pt uses remote sharing to facilitate telemedicine visit!
  - Bottom line: what is approved by insurance!!

34

34

Other user factors

35

35

Another Case: Jack, 66 year-old male

- Type 2 diabetes for over 15 years, long history of poor control
- Last a1c 7.3%
- But he reports fasting glucose levels consistently below 140 in the morning

36

36

Jack's CGM AGP

- 66 year-old with Type 2 for 5 years
- Meds
  - Metformin 1000mg BID
  - Dapa 10 mg daily
  - Glimeperide 2 mg daily with breakfast
- A1c 7-7.5%
- BMI 33

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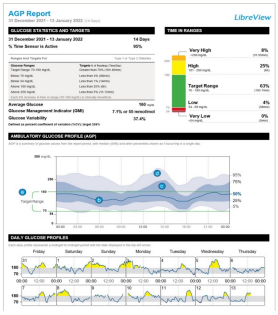
37

Jack

- D—download data
- A—assess safety
- T—TIR
- A—Areas for improvement
- A– Action plan



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38

Jack's AGP

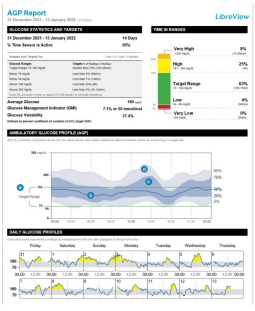
Days active?

Lows?

TIR?

Areas for improvement?

Action plan?



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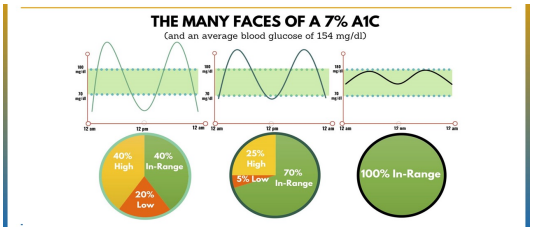
A1c can be deceiving….

***1% = 15 minutes in 24 hours



Diatribe online

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Dexcom G6

- Uses 10 day sensor, measures data every 5 minutes, 2 hour warm-up
- G6 has transmitter that needs changed every 3 months
- Can use it with receiver or smart phone (or both)
- Alarms monitor for lows, highs
  - < 55 mg/dL cannot be turned off
- G6 can be used with Tandem T:Slim pump, IQ Technology or Omni Pod Dash, OP5
- G7 recently approved with Tandem T-Slim pump
- Download data to Clarity for sharing with HC team
- Can be worn on arm or abdomen

41

41

Dexcom G7

- Can be used with Tandem T-slim insulin pump
- Smaller, size of 3 stacked quarters
- Sends data every minute
- Sensor lasts 10 days
- Combined transmitter and sensor (no separate transmitter needed)
- 27-30 minute warm up period

42

42

Dexcom Stelo BioSensor

- FDA approved March 2024
- **Will be first OTC CGM!**
- Adults with and without DM
- Not designed for problematic hypoglycemia due to lack of alarms
- Lasts 15 days, worn on arm
- Pairs with smart phone or device
- Records glucose every 15 minutes
- Will be available Summer 2024

Dexcom Stelo Glucose Biosensor

43

Libre 1, 2

- Measures when scanned, now recording more frequently but still needs scanned
- Cannot ingest high doses Vit C (false highs obtained)
- Has to be scanned by user minimally every 8 hours
- Libre 2 uses high and low alarms
- No alarm with Libre 1
- 1 hour warm up period
- Needs calibrated with fingerstick in first 12 hours
- Links with Libreview for data download with HC team

44

44

Libre 3

- Much smaller (2 stacked pennies)
- No scanning needed
- Generates data every 1 minute
- Has alarms
- 14 day sensors
- One piece insertion
- 33 feet Bluetooth range
- Can use with smart phone, no need for reader (unless Medicare)

45

45

Libre 2 PLUS

- The first 15-day CGM sensor in the US* is now authorized to work with the Tandem t:slim X2 insulin pump with Control-IQ technology.

46

46

Medtronic Guardian Sensor 3, 4

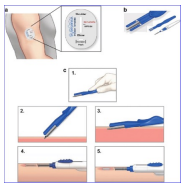
- Work with Medtronic Insulin Pump
  - Medtronic 3
    - Worn 7 days, has 2 hour warm up period
    - Needs calibrated twice a day (3)
    - Uses with 670G, 770G
  - Medtronic 4
    - does not need calibrations
    - Has alarms
    - Can be used with AI generated diabetes coached food and exercise app (Sugar.IQ)
    - Can be used with Med. 780G

47

47

Senseonics Eversense E3

- Implantable sensor
- Lasts 180 days, needs 24-hour warm-up period
- Reads every 5 minutes
- Uses external transmitter that vibrates, is wearable
- Needs calibrated twice daily for first 21 days, then daily
- Has vibrating alarms, connects via cell phone
- MRI safe sensor
- Sensor requires invasive procedure to insert and remove



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48

Lucy, 62 year-old female

History of DM, HF, neuropathy, obesity
Meds: glargine U-300 (Toujeo) 50 units daily
Aspart 10 units TID AC
A1c 6.4%
Rarely takes blood glucose levels
Too tired to exercise
Has frequent episodes with Hypo symptoms
Let's give her a CGM!

49

49

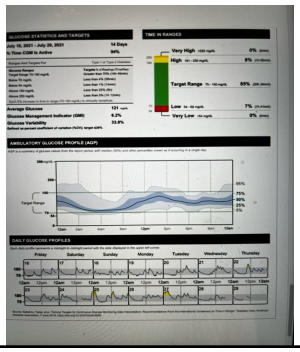
Lucy-- AGP

What do you notice?

TIR?

CV?

Time in hypo?



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Lucy

- What is action plan ?

- Start GLP1ra
- Stop aspart as she titrates GLP1ra up
- Lower basal insulin by 10%
- Give her Rx for CGM
- Send to dietitian to discuss dietary issues

51

51

Assist with setting alarms on CGM device

- Low glucose alarm
- High glucose alarm
- Signal loss
- Low threshold alarm

- Patients experience alarm fatigue! Keep alarms realistic!

52

52

Patient Teaching Points

- How to apply CGM and set it up
  - Clean dry skin, can use Skin Tac if it's not sticking
  - Can apply fluticasone to site if rash or pruritis occurs.
- Use of directional arrows –trends
- Sharing data with your clinic
- Rotate sensor sites, assess skin issues
- Keep phone or reader close by at all times
- Personalize alarms

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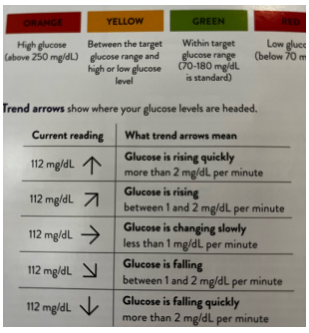

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Substances that can interfere with CGM

CGM Category	rtCGM			is-CGM
	Dexcom G6	Medtronic Enlite 2 and Guardian 3	Senseonics Eversense	Abbott Freestyle Flash Libre 1 and 2
Chemical substances interferences	Hydroxyurea Repeated doses of acetaminophen (>4 gm/day)	Acetaminophen Ethanol/Wine Albuterol Lisinopril Atenolol Atorvastatin Ascorbic Acid	Tetracycline Mannitol	Ascorbic Acid (1-3g daily) Salicylic Acid (>650 mg daily)
Interferences from Radiological Studies	No impact from XRay, CT or angiography among hospitalized patients There is some migration from MRI	Medtronic recommends that users remove the sensor in the presence of X-ray, CT, MRI PET, Airport scanners	Close contact with direct Electromagnetic interference (EMI) may interfere with the smart transmitter's ability to send data to the mobile device	Limited evidence of in-vitro exposure to Xray and RT, CT or MRI did not impact the data recorded by Libre Pro in 10 sensors

55

55

Sharing data with clinic

- Develop clinic processes with CGM
- Staff can apply CGM and do pt teaching
- Make sure they sign up at that visit for remote sharing of data—Tip! Make it mandatory!
- Devices
  - Freestyle Libre
    - Share data via Libreview app
  - Dexcom
    - Share with Dexcom Clarity app.
  - Can use Glooko or Tidepool for downloads
  - Medtronic—uses its own download system

56

56

Tips for Use in Clinic

- Have clinic champion or super user
- Relationship with DME companies
- Develop clinic work-flow
  - How to easily download data for use by clinician
  - How to upload into EMR
- Group classes to facilitate mass education
- Get samples to facilitate process
- Develop dot phrases for CGM into practice notes in EMR

57

57

Summary

- Professional CGM
  - Valuable tool to gain insight about patient's glycemia challenges
  - Will offer opportunity to engage patient in CGM process
- Personal CGM
  - Will see better glycemic outcomes
  - Lowers a1c, helps avoid hypo events and keeps pt safer with alarms
- Reimbursement
  - Supports clinic organization and work-flow efforts
  - Meet with billing department to ensure financial benefits are realized
  - Trouble shoot coding/billing denials

58

58

Other References

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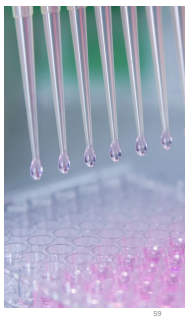


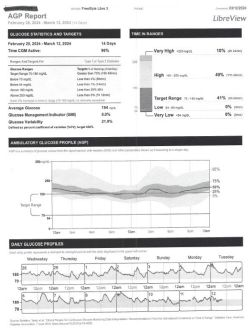
59

59

Case: 63 year-old male, ESRD history
Ron

- T2D for over 15 years
- Last a1c 8.2%
- On Xultophy 12-14 units daily

- Finally obtained CGM!



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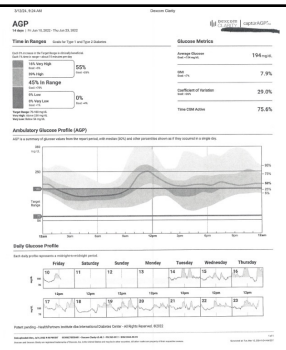
Another one to ponder…

Janet, 63 y/o
Type 2
On basal-bolus insulin
A1c .9%



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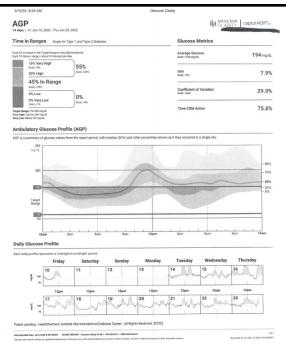
Janet

- Data download
- Assess
- TIR
- Action plan
- Areas for Improvement



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62

Reminder: Types of patients to target for CGM to get you started.

- Multiple insulin injections daily
- Hypoglycemia risks
- Insulin pump users
- Frequent hypo events
- History of poor control
- Pregnancy
- Pre-diabetes (controversial)

63

63

Codes and description	Medicare physician office fee schedule[1]	Medicare outpatient diabetes center[2]	Private payor (2023 averages)[3]	Relative value unit (RVU) non-facility[1]
CGM Servic				
CPT 95249 **Personal CGM - Starting/Training** Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording. *Bill only once during the time period that the patient owns the device.**	$61.67	$57.48 APC 5733	$150	1.82
CPT 95250 **Professional CGM** Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor 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. *Do not bill more than 1x/month.**	$147.07	$120.86 APC 5012	$320	4.34
CPT 95251 **CGM Interpretation** Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report. *Do not bill more than 1x/month.**	$34.56	Paid under physician fee schedule	$98	1.02

64

64